ORAL ARGUMENT NOT SCHEDULED

No. 19-1120

IN THE

United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

In re Scottsdale Research Institute, LLC,

Petitioner

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ON PETITION FOR A WRIT OF MANDAMUS TO WILLIAM P. BARR, U.S. ATTORNEY GENERAL, UTTAM DHILLON, ACTING ADMINISTRATOR OF THE U.S. DRUG ENFORCEMENT ADMINISTRATION, AND THE U.S. DRUG ENFORCEMENT ADMINISTRATION

Amended Petition for a Writ of Mandamus

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GLOSSARY

APA	Administrative Procedure Act
CSA	Controlled Substances Act
DEA	U.S. Drug Enforcement Administration
Decl.	Declaration of Suzanne Sisley, M.D.
DOJ	U.S. Department of Justice
Ex.	Exhibit (Appendix)
FDA	U.S. Food and Drug Administration
HHS	U.S. Department of Health and Human Services
MAPS	Multidisciplinary Association for Psychedelic Studies
NIDA	National Institute on Drug Abuse
PTSD	Post-Traumatic Stress Disorder
SRI	Scottsdale Research Institute, LLC

PRELIMINARY STATEMENT

Dr. Sue Sisley did everything by the book. Over the course of a decade, she ran the regulatory gauntlet, earning the blessing of four federal agencies so that she could do groundbreaking clinical research into the efficacy of cannabis to treat veterans suffering from treatment-resistant post-traumatic stress disorder ("PTSD")—some of whom turn to suicide. Through her company, Scottsdale Research Institute, LLC ("SRI"), the Petitioner in this case, she wants to continue that research and investigate other potential applications for cannabis. But poor-quality government cannabis is preventing that from happening.

To comply with federal law, SRI must use federally-sourced cannabis, grown exclusively on a single 12-acre farm run by the University of Mississippi. SRI used this cannabis for its Phase II trials. It arrived in powdered form, tainted with extraneous material like sticks and seeds, and many samples were moldy. Whatever reasons the government may have for sanctioning this cannabis and no other, considerations of quality are not among them. It is not suited for any clinical trials, let alone the ones SRI is doing. Simply put, this cannabis is sub-par.

Thirty months ago, Sisley thought she had a fix. After the Drug Enforcement Administration ("DEA") announced a new policy designed to increase the number of entities permitted to manufacture cannabis for clinical trials and other research endeavors, SRI applied to grow cannabis for its clinical research. Allowing SRI to grow its own cannabis will improve drug quality and give it tighter control over dosages. But the agency has yet to respond. With new trials around the corner, SRI can wait no longer.

And it shouldn't have to. Before Sisley submitted SRI's application, Congress amended the Controlled Substances Act ("CSA") to address this problem. As part of the "Improving Regulatory Transparency for New Medical Therapies Act," it added a requirement that the Attorney General, upon receiving an application to manufacture a Schedule I substance for use only in a clinical trial, publish a notice of application not later than 90 days after accepting the application for filing. 21 U.S.C. § 823(i)(2).

That date was more than two years ago.

Thus, agency action has been unlawfully withheld. And in view of an express directive to prioritize applications relating to clinical research, agency action has most certainly been unreasonably delayed.

To determine whether to issue a writ of mandamus to compel agency action, this Court applies the six-part "*TRAC*" standard. This case passes

the test: the agency has flouted a non-discretionary deadline to complete a perfunctory—but vitally important—task; significant economic interests and human health and welfare are at stake; it cannot be said that expediting delayed action will interfere with agency activities of a higher or competing priority; and mandamus is warranted regardless of the purity of the motives underlying DEA's unexplained delay.

SRI turns to this Court having exhausted all other avenues of relief. Sisley reached out to the agency no fewer than five times, the media has done a full-court press, and the number of letters from frustrated members of Congress from both parties imploring the agency to act is quickly approaching a dozen. At this juncture, nothing short of a writ from this Court compelling the agency to act will stop the ongoing harm caused by DEA's unlawful and unreasonable delay.

RELIEF SOUGHT

SRI seeks a writ of mandamus directing the Attorney General, DEA, or its Acting Administrator to issue a "notice of application" by 90 days from the date of service of this amended petition or fifteen days after the writ issues, whichever is later.

JURISDICTIONAL STATEMENT

This petition arises under the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 555(b), 702, and 706(1). DEA's failure to issue a notice of SRI's application is agency action both unlawfully withheld and unreasonably delayed.

The Controlled Substances Act, 21 U.S.C. § 801 et seq., authorizes direct review in this Court of all final determinations, findings, and conclusions of the Attorney General or agency decisions, *id.* § 877. Because agency delay can thwart judicial review, this Court may resolve claims of unreasonable delay "to protect its future jurisdiction." *Telecomms. Research & Action Ctr. v. FCC*, 750 F.2d 70, 76 (D.C. Cir. 1984) ("*TRAC*"); *Gottlieb v. Pena*, 41 F.3d 730, 734 (D.C. Cir. 1994). "Were it otherwise, agencies could effectively prevent judicial review of their policy determinations by simply refusing to take final action." *Cobell v. Norton*,

240 F.3d 1081, 1095 (D.C. Cir. 2001). Finally, the All Writs Act, 28 U.S.C. § 1651(a), permits this Court to issue writs of mandamus to cure unreasonable delay. *TRAC*, 750 F.2d at 75.

ISSUE PRESENTED

After DEA announced a new policy designed to increase the number of entities permitted to manufacture cannabis for clinical trials and other research endeavors, SRI applied to manufacture cannabis to support its own FDA-approved clinical trials. Yet thirty months have passed since SRI filed its application, and the agency has done nothing.

Thus, SRI's petition presents two questions:

1. Has the DEA unlawfully withheld or unreasonably delayed agency action under 5 U.S.C. § 706(1)? and
2. Should this Court issue a writ of mandamus under 28 U.S.C. § 1651(a) to compel the agency to issue the statutorily required notice?

STATEMENT OF THE CASE

The CSA regulates the production, possession, and distribution of controlled substances. *See* 21 U.S.C. § 801 et seq. It contains five schedules of drugs, based on their accepted medical uses, their potential for abuse, and their psychological and physical effects on the body, with Schedule I being the most restrictive. *Gonzales v. Raich*, 545 U.S. 1, 13-14 (2005). Schedule I substances cannot be used, except in research. *See id*. at 14.

When Congress enacted the CSA in 1970, it made cannabis a Schedule I drug. *Id*. It did so based, in part, on a recommendation from the Assistant Secretary of the U.S. Department of Health, Education, and Welfare that cannabis be placed in Schedule I "at least until the completion of certain research." *Id*.

Although the CSA provides a mechanism to administratively reschedule cannabis without legislative intervention, *see* 21 U.S.C. § 811, neither DEA nor the Attorney General has ever exercised that prerogative. In fact, DEA repeatedly rejects requests to reschedule. Most recently, in August 2016, it denied a petition from the states of Rhode Island and Washington. *See* Ex. 16 (A157). The agency's rationale for refusing to reschedule is always the same: the dearth of clinical trials demonstrating

cannabis's medical efficacy. *See, e.g.*, *id.* at A154. ("[T]here are no adequate and well controlled studies proving efficacy.").

I. Through a "closed" regulatory regime, DEA tightly controls clinical research with controlled substances.

a. Registration framework.

The CSA establishes a "closed" registration system. *Raich*, 545 U.S. at 13. Manufacture and distribution may occur only among registered handlers of controlled substances, referred to as "registrants." *See id.*; 21 C.F.R. § 1300.02(b) (2017). Thus, anyone seeking to manufacture or distribute a controlled substance must apply to DEA. 21 U.S.C. § 822(a)(1). DEA grants a registration if it determines that doing so is consistent with (1) the public interest and (2) U.S. obligations under the Single Convention on Narcotic Drugs, 1961. *Id.* § 823(a).

DEA has promulgated rules and regulations to implement these registration requirements. *See id.* § 821. 21 C.F.R. § 1301.13 (2014), for example, establishes application fees. Section 1301.14(c) explains how DEA processes applications:

> Applications submitted for filing are dated upon receipt. If found to be complete, the application will be accepted for filing. Applications failing to comply with the requirements of this part will not generally be accepted for filing. In the case of minor defects as to completeness, the Administrator may accept the application for filing with a request to the applicant for additional information. A defective application will be returned

> to the applicant within 10 days following its receipt with a statement of the reason for not accepting the application for filing. A defective application may be corrected and resubmitted for filing at any time; the Administrator shall accept for filing any application upon resubmission by the applicant, whether complete or not.

21 C.F.R. § 1301.14(c) (2010).

DEA's authority over the registration process is not without limits. For example, the agency must register only the number of bulk manufacturers of a Schedule I or II substance necessary to "produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes." 21 U.S.C. § 823(a)(1); 74 Fed. Reg. 2,101, 2,127-2,130 (Jan. 14, 2009) (discussing section 823(a)(1)). From the time it was passed in 1970 until 2015, however, the CSA placed no deadlines on DEA's duty to process applications to manufacture controlled substances.

b. Delays in processing applications and scheduling.

Without deadlines, DEA could delay processing applications—even those seeking to facilitate clinical research—for years, with little recourse available to the applicant. These delays can be detrimental to innovation and public health, and they began to cause problems as the CSA moved into the 21st century.

The cases of Belviq and Fycompa are illustrative. *See generally Eisai, Inc. v. FDA*, 134 F. Supp. 3d 384, 387 (D.D.C. 2015) (chronicling the two drugs' stories). The U.S. Food and Drug Administration ("FDA") approved Belviq in June 2012, but the U.S. Department of Health and Human Services ("HHS") recommended the drug for scheduling. With no timetable governing its review, DEA took another year to approve the drug's placement in Schedule IV, delaying its entry into the market. *Id.* at 389. The story with Fycompa, a drug used to treat seizures in patients suffering from epilepsy, is largely the same. *See id.* In fact, the agency's fourteen-month delay led Eisai to seek mandamus from this Court.[1]

Problems with delay were felt all-around, including with controlled substances like cannabis. In one notable instance, an applicant waited more than three years after applying before the agency responded, proposing a denial. *Craker v. DEA*, 714 F.3d 20-21 (1st Cir. 2013). The saga spanned an entire decade, start to finish. *Id.* at 29.

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[1] Eisai filed a petition in this Court on August 13, 2013. *See In re Eisai Inc.*, No. 13-1243, Doc. 1452261 (D.C. Cir.). Eisai argued that DEA's failure to timely schedule Fycompa was unreasonable and asked the Court to intervene. DEA responded that it expected to act by the end of October. *Id.* at Doc. 1454740. Then, through an October 17, 2013 notice, DEA informed the Court that the rule was submitted for publication in the Federal Register. The Court denied the mandamus petition the next week. *Id.* at Doc. 1462438.

c. Congress adds statutory deadlines to address opaqueness and delay in DEA's processing of a single class of applications: those seeking to manufacture for clinical trials.

In 2015, Congress passed the "Improving Regulatory Transparency for New Medical Therapies Act," H.R. No. 639, Pub. L. No. 114-89, 129 Stat. 703 (2015). Relevant here, the Act added section 823(i)(2), which requires the Attorney General to notice applications to manufacture Schedule I substances for clinical research not later than 90 days after the application is "accepted for filing":

> For purposes of registration to manufacture a controlled substance under subsection (a) for use only in a clinical trial, the Attorney General shall, in accordance with the regulations issued by the Attorney General, issue a notice of application not later than 90 days after the application is accepted for filing. Not later than 90 days after the date on which the period for comment pursuant to such notice ends, the Attorney General shall register the applicant, or serve an order to show cause upon the applicant in accordance with section 824(c) of this title, unless the Attorney General has granted a hearing on the application under section 958(i) of this title.

21 U.S.C. § 823(i)(2).

The purpose of the amendment was clear: to improve transparency and to prioritize applications relating to clinical research. In a section titled "Background and Need for Legislation," the House Report underscores three needs triggering the new "timetable": (1) addressing "[i]nconsistency and lengthy review times at DEA," (2) distinguishing between

"manufacturing of a controlled substance *for marketing* and the manufacturing of a controlled substance *for use in clinical trial*," and (3) putting in place a "*transparent process* for the applicant to determine the reasons for a delay in the application." Ex. 18 at A168-69 (emph. added).

II. SRI falls within the class of researchers Congress sought to protect from delay.

SRI is an Arizona company dedicated to clinical research. To date, it is the only entity federally approved to do clinical research into the effects of cannabis on veterans with treatment-resistant PTSD. SRI does not encourage or sanction recreational cannabis use, but it does support research to determine the applicability of cannabis as medicine. *See* Decl. at ¶ 2.

The journey of SRI's principal, Dr. Sue Sisley, is well-documented. Over a decade ago, she treated veterans with PTSD in her private practice. Sisley prescribed approved medicines on the market, but discovered that for some, none helped. Many clients disclosed that cannabis worked better. For some, it was the only thing that worked. These experiences inspired her to do clinical research into the safety and efficacy of cannabis with veterans suffering from PTSD. *See* Decl. at ¶¶ 7-11.

Little did she know how difficult it would be. Start to finish, it took her *seven* years to amass the necessary approvals just to *begin* the study.

Unlike other controlled substances, clinical research with cannabis requires obtaining approval from four federal agencies, on top of Institutional Review Board approval. *See* Decl. at ¶¶ 8-19 & n.8 (discussing CNN's Weed 3 documentary); *see also* Ex. 21 (A179) (Rolling Stone article titled "Why Is It So Hard to Study Pot?"). She put together a protocol in 2009, which the FDA approved in 2011. Over the next three years, Sisley secured the approvals of the United States Public Health Service and the National Institute on Drug Abuse ("NIDA"), which was necessary to acquire cannabis for the study. Finally, after other significant setbacks, she obtained a Schedule I research license from DEA in April 2016. Only after obtaining these approvals could the research proceed. *See* Decl. at ¶¶ 12-18.

In January 2017, SRI, with the support of the Multidisciplinary Association for Psychedelic Studies ("MAPS"), began its triple-blind clinical study of smoked whole-plant cannabis to treat PTSD symptoms in veterans. A $2.1 million grant to MAPS from the Colorado Department of Public Health and Environment funded the study. Phase II trials[2] finished in

[2] Phase II trials aim to determine if a treatment works, and usually involve 25 to 100 study subjects. Phase III trials compare the safety and effectiveness of a drug against other treatments and involve far more study subjects.

February 2019. *See* Decl. at ¶ 19. As we next explain, however, low-quality government cannabis hampered the research.

Additional trials with veterans are imminent. SRI also hopes to begin clinical trials to assess the efficacy of cannabis to treat breakthrough pain in cancer patients soon. *See* Decl. at ¶ 26.

III. The current supply of federally legal cannabis stifles clinical research.

a. The NIDA monopoly.

For almost 50 years, the only legal source of cannabis for research in the United States has been a single farm at the University of Mississippi. *See generally Craker*, 714 F.3d at 20 (1st Cir. 2013); Ex. 16 at A158 (81 Fed. Reg. 53,846) ("For nearly 50 years, the United States has relied on a single grower to produce marijuana used in research.").

The quality of the cannabis from this farm—and its delivery logistics—are poor. Some has languished on the shelves for years. It looks more like green talcum powder than medical grade cannabis, Decl. at ¶ 21 & n.11:

Most samples SRI received contained extraneous plant material like sticks and seeds. Ex. 14 at A149-A152 (Lab Report). Others had mold. *See id.* at A146. Also, the government demands researchers indemnify the government to use this study drug, *see* Decl. at ¶22:

SRI complies with federal law, so it had to use this cannabis. Unfortunately, its poor quality undermined results. For example, Sisley observed that sticks and seeds caused bronchial irritation in some subjects. Decl. at ¶ 23. SRI is reticent to indemnify the government, especially because it has told the government it is willing and able to manufacture its own, on-site, high-quality, fresh cannabis under the agency's strict regulations and supervision. *See id.* at ¶ 24. This cannabis is inadequate for a third important reason: Phase III trials require cannabis virtually identical to material used in proposed pharmaceutical medicine. *See id.* at ¶ 25.

Now, SRI looks north of the border for true medical-grade cannabis, because the cannabis from NIDA falls short. *See id.* at ¶ 26.

b. To address supply issues, DEA solicits applications to register additional manufacturers of cannabis for clinical research.

On August 12, 2016, DEA denied a petition from Rhode Island and Washington to reschedule cannabis as a Schedule I substance. Ex. 15 (A153) (81 Fed. Reg. 53,687 (Aug. 12, 2016)). But it also committed to improving the supply of cannabis suitable for clinical research.

DEA explained: "the available evidence is not sufficient to determine that marijuana has an accepted medical use" and "more research is needed into marijuana's effects, including potential medical uses for marijuana and its derivatives." *Id.* at A155 (81 Fed. Reg. at 53,689). In the letter accompanying the denial, DEA declared "[r]esearch . . . the bedrock of science," and committed to "support and promote legitimate research regarding marijuana and its constituent parts." Ex. 22 at A194.

Consistent with that goal, DEA issued a separate notice announcing a new policy to increase the number of entities registered to manufacture cannabis. Ex. 16 (A157) (81 Fed. Reg. 53,846 (Aug. 12, 2016)). DEA declared its "full[] support" of cannabis research and "concluded that the best way to satisfy the current researcher demand for a variety of strains of

marijuana and cannabinoid extracts is to increase the number of federally authorized marijuana growers." *Id*. at A158.

c. Answering DEA's call, SRI applies to manufacture cannabis for its clinical research.

Shortly after DEA's August 2016 policy statement, SRI applied to manufacture cannabis to support its clinical research. Ex. 1 (A001) (Oct. 2016 Application); Decl. at ¶ 27. Weeks later, Sisley answered a supplemental questionnaire the agency had remitted. Ex. 2 (A005) (Questionnaire); Decl. at ¶ 28. Asked how cannabis grown by SRI would be used, Sisley stated that the existing supply was not adequate for its clinical trials:

> [SRI] is preparing for phase 3 FDA approved drug development clinical trials with cannabis. Our ultimate goal involves evaluating whether cannabis can be turned into a prescription medicine. The only way to conduct this analysis is through phase 3 trials. However the current supply of research cannabis from cannot be utilized for prescription drug development. It can only be used for academic research. Which is why we are seeking to cultivate a new supply of cannabis to be used for these Phase 3 FDA trials.

Ex. 2 at A011. Sisley also told DEA that SRI could supply other clinical trials in the future. *See id*. at A008, 010, 012.

d. After soliciting applications, DEA processes none of them.

The number of applications the agency has processed since August 2016 is zero.

This delay is unusual, unprecedented even. The typical time from application submission to a notice in the Federal Register is months, not years. A 2016 DEA presentation says the process takes *as much* as 4-6 months to complete. Ex. 3 at A083 (DEA Presentation). DEA routinely processes applications within this timeframe:

- On December 12, 2018, Siemens Healthcare Diagnostics Inc. applied to be a bulk manufacturer of Ecgonine, a Schedule II substance. A notice in the Federal Register followed on March 21, 2019. 84 Fed. Reg. 10,534.
- On October 12, 2018, Johnson Matthey Inc. applied to be a bulk manufacturer of Schedule I and II substances. A notice in the Federal Register followed on February 21, 2019. 84 Fed. Reg. 5,477.
- On August 22, 2018, Insys Manufacturing, LLC applied to be a bulk manufacturer for Marijuana and Tetrahydrocannabinols to produce synthetic ingredients for product development and distribution to customers. A notice in the Federal Register followed on March 21, 2019. 83 Fed. Reg. 54,611.

The agency approved eight applications in September 2017, *see* 82 Fed. Reg. 44,842 (Sept. 26, 2017), and seven more in May 2018, *see* 83 Fed. Reg. 22,518 (May 15, 2018). In short, these applications do not take years to process.

e. Substantial efforts to obtain agency action without Court intervention have failed.

Sisley has repeatedly reached out to DEA to check the status of SRI's application. *See, e.g.*, Ex. 13 (A139) (Aug. 30, 2018 e-mail); *see also* Decl ¶¶ 30-31. Every time, the message is the same: no progress.

This unusual delay has sparked media attention. *See, e.g.*, Ex. 19 (A170) (article titled "Marijuana-Research Applications Go Nowhere at Justice Department"); Ex. 20 (A174) (article titled "Justice Department at Odds with DEA on Marijuana Research, MS-13" explaining how government officials were "sitting on" applications and that DOJ "effectively shut down" the program). Members of Congress from both sides of the aisle have repeatedly asked the Attorney General and DEA for status updates:

- **April 12, 2018:** former Senator Hatch and Senator Harris ask for an update on applications to manufacture cannabis for research and a commitment to resolve outstanding applications by August 11, 2018. Ex. 5 (A107).
- **July 25, 2018:** a bipartisan group of eight senators inquire about the status of the applications and request answers by August 10. Ex. 9 (A124).
- **August 30, 2018:** a bipartisan group of congressmen write to the Secretary of Veterans Administration about the need to conduct "a rigorous clinical trial into the safety and efficacy of medicinal cannabis for veterans with post-traumatic stress disorder (PTSD) and

chronic pain so that we can better understand the potential benefits or dangers of medicinal cannabis." Ex. 6 (A112).

- **August 31, 2018:** another bipartisan group of congressmen urge DEA to end the delay. Ex. 7 (A115).
- **September 28, 2018:** another bipartisan group of fifteen congressmen express concern over DEA's delay. Ex. 8 (A119).
- **March 28, 2019:** Senators Schatz and Booker urge the Attorney General to move forward. Ex. 10 (A128).
- **April 2, 2019:** another bipartisan group of six senators question DEA's efforts to process applications. Ex. 11 (A131).
- **May 7, 2019:** another bipartisan group of *thirty* congressmen urge the agency to do more "because the matter is of such importance." Ex. 12 (A135).

To SRI's knowledge, neither the Attorney General nor DEA has responded to *any* of these inquiries. In fact, as of December 28, 2018, DEA reported that it "continues to review applications for registration . . . ." 83 Fed. Reg. 67,348, 67,350 (Dec. 28, 2018). Thus, well past the two-and-a-half-year mark, SRI's application continues to languish in agency purgatory.

SUMMARY OF THE ARGUMENT

DEA's delay in noticing or responding to SRI's application is unlawful, unreasonable, and egregious. It contravenes the letter and spirit of the CSA, seriously harms SRI, and hampers SRI's efforts to help suffering veterans through clinical research. Everyone—including the agency—agrees that this research is important and that the need for research generally is urgent. Here, DEA can act with little expenditure of resources.

The Court should issue the extraordinary writ of mandamus because DEA's inexplicable delay is the only remaining impediment to research of urgent importance to the health and welfare of millions of Americans.

STANDING

When a claim is based on an alleged deprivation of a procedural right, such as the right to have an agency process an application consistent with congressional command, "the primary focus of the standing inquiry is not the imminence or redressability of the injury to the [petitioner]" but instead whether "the government act performed without the procedure in question will cause a distinct risk to a particularized interest of the plaintiff." *City of Dania Beach v. FAA*, 485 F.3d 1181, 1185 (D.C. Cir. 2007) (cites omitted). A petitioner in such a case "never has to prove that if he had received the

procedure the substantive result would have been altered." *Sugar Cane Growers Co-op. of Fla. v. Veneman*, 289 F.3d 89, 94 (D.C. Cir. 2002). Instead, "[a]ll that is necessary is to show that the procedural step was connected to the substantive result." *Id.* at 94-95.

Petitioner has standing because it is suffering an injury directly traceable to DEA's delay in processing its application that can be redressed by the relief requested. *See generally Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992). Petitioner submitted its application to manufacture cannabis for use in clinical trials and paid DEA thousands of dollars. *See* Ex. 4 at A106 (showing application fee). Under the plain language of both section 823(i)(2) and the APA, Petitioner was entitled to have DEA issue a notice regarding its application in the Federal Register to commence the process for determining whether Petitioner should be registered under the Act. 21 U.S.C. § 823(i)(2); 81 Fed. Reg. at 53,848. Petitioner and its patients have suffered other harms as well from the agency's inaction, including being saddled with cannabis ill-suited for clinical research.

ARGUMENT: REASONS WHY THE WRIT SHOULD ISSUE

I. Legal Standard

To show entitlement to mandamus, SRI must demonstrate: "(1) a clear and indisputable right to relief, (2) the government agency or official is violating a clear duty to act, and (3) that no adequate alternative remedy exists." *Am. Hosp. Ass'n v. Burwell*, 812 F.3d 183, 189 (D.C. Cir. 2016) (citing *United States v. Monzel*, 641 F.3d 528, 534 (D.C. Cir. 2011)). These requirements are jurisdictional; unless all are met, the Court must dismiss. *Id.* (cites omitted). "Even when the legal requirements for mandamus jurisdiction have been satisfied, however, a court may grant relief only when it finds compelling equitable grounds." *Id.* (quoting *In re Medicare Reimbursement Litig.*, 414 F.3d 7, 10 (D.C. Cir. 2005)). SRI must therefore show that its "right to issuance of the writ is clear and indisputable." *Id.* (quoting *Power v. Barnhart*, 292 F.3d 781, 784 (D.C. Cir. 2002)).

Mandamus claims like SRI's that "target agency delay[] turn on 'whether the agency's delay is so egregious as to warrant mandamus.'" *Id.* (quoting *In re Core Commc'ns, Inc.*, 531 F.3d 849, 855 (D.C. Cir. 2008)). In making that assessment, this Court looks to the so-called "*TRAC* factors"

> (1) the time agencies take to make decisions must be governed by a "rule of reason"; (2) where Congress has provided a timetable or other indication of the speed with which it expects

> the agency to proceed in the enabling statute, that statutory scheme may supply content for this rule of reason; (3) delays that might be reasonable in the sphere of economic regulation are less tolerable when human health and welfare are at stake; (4) the court should consider the effect of expediting delayed action on agency activities of a higher or competing priority; (5) the court should also take into account the nature and extent of the interests prejudiced by delay; and (6) the court need not "find any impropriety lurking behind agency lassitude in order to hold that agency action is 'unreasonably delayed.'"

TRAC, 750 F.2d at 80 (cites omitted).

"[W]here the statute imposes a deadline or other clear duty to act, the bulk of the *TRAC* factor analysis may go to the equitable question of whether mandamus *should* issue, rather than the jurisdictional question of whether it *could*." *Am. Hosp. Ass'n*, 812 F.3d at 189-90. That is the case here. Accordingly, SRI folds its discussion of the first two jurisdictional requirements into its analysis of the *TRAC* factors and addresses the only remaining jurisdictional issue—whether an adequate alternative remedy exists—separately.

II. DEA's egregious delay warrants mandamus.

DEA's "recalcitrance . . . in the face of a clear statutory duty" calls out for mandamus. *Pub. Citizen Health Research Grp. v. FDA*, 740 F.2d 21, 32 (D.C. Cir. 1984) (citing 5 U.S.C. §§ 555(b), 706(1)). The first five *TRAC* factors strongly favor the exercise of equitable discretion, and the sixth—improper conduct or motive—is not a prerequisite for mandamus. *TRAC*,

750 F.2d at 80. The APA commands DEA "to conclude a matter presented to it within a reasonable time," 5 U.S.C. § 555(b), and courts must "compel agency action unlawfully withheld or unreasonably delayed," *id.* § 706(1). If those imperatives apply anywhere, they apply here.

a. Congress's mandate that DEA "issue a notice of application not later than 90 days after the application is accepted for filing" supplies the applicable rule of reason.

Of the six *TRAC* factors, "[t]he first and most important . . . is that 'the time agencies take to make decisions must be governed by a "rule of reason."'" *In re Core Comm'cns, Inc.*, 531 F.3d at 855 (quoting *TRAC*, 750 F.2d at 80). Even absent an express statutory deadline, this factor can weigh in favor of mandamus. But as the second *TRAC* factor clarifies, the analysis is simpler where "Congress has provided a timetable or other indication of the speed with which it expects the agency to proceed." *TRAC*, 750 F.2d at 80. When Congress commands an agency to complete a discrete, ministerial duty within a defined timeframe, the "statutory scheme suppl[ies] content for this rule of reason . . . ." *Id.*

That is the case here. Section 823(i)(2)'s command that DEA "shall, in accordance with the regulations issued by the Attorney General, issue a notice of application not later than 90 days after the application is accepted for filing," imposes a non-discretionary duty on DEA to take a discrete,

ministerial action. 21 U.S.C. § 823(i)(2). The statute conveys both a clear duty (on DEA) and an equally clear right (on SRI). Once SRI's application was accepted for filing, DEA had a duty to "issue a notice of [SRI's] application," and SRI's indisputable right to receive that notice within "90 days" arose automatically. *See* Ex. 16 at A160 (recognizing applicants' "due process" interest in having DEA process application to manufacture).[3]

In cases like this one, where Congress has given the agency a *specific* task to complete within a *relatively brief* timeframe, this Court has described "Congress's intent that that agency act promptly" as "manifest[ ]." *In re People's Mojahedin Org. of Iran*, 680 F.3d 832, 837 (D.C. Cir. 2012); *compare, e.g.*, *Baptist Mem. Hosp. v. Sebelius*, 603 F.3d 57, 63 (D.C. Cir. 2010) (denying mandamus relief because there is no clear duty to act where the statutory language—"may"—is permissive and not mandatory). Although there "is 'no *per se* rule as to how long is too long' to wait for agency action," this Court has held that "a reasonable time for agency action is typically counted in weeks or months, not years." *In re Am. Rivers and Idaho Rivers United*, 372 F.3d 413, 419 (D.C. Cir.

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[3] Of course, the agency also has a duty not to unreasonably delay agency action under the APA. *See* 5 U.S.C. §§ 555(b), 706(1). The 90-day deadline confirms that Congress intended reasonable delay to be months, not years.

2004) (quoting *In re Int'l Chem. Workers Union*, 958 F.2d 1144, 1149 (D.C. Cir. 1992) (per curiam)); *see also, e.g.*, *MCI Telecomms. Corp. v. FCC*, 627 F.2d 322, 327 (D.C. Cir. 1980) (over three years); *Midwest Gas Users Ass'n v. FERC*, 833 F.2d 341, 359 (D.C. Cir. 1987) (four years).

In *People's Mojahedin*, for example, this Court held that a twenty-month failure to act on a 180-day statutory deadline "plainly frustrates the congressional intent and cuts strongly in favor of granting [the] mandamus petition." 680 F.3d at 837. DEA's inaction in this case is far more egregious: in the face of a command to complete a ministerial act due in half the time, the agency has unlawfully withheld the required action for almost twice as long. If an agency's refusal to act that exceeds the statutory timeframe by 333% "cuts strongly in favor of granting [the] mandamus petition," as this Court held in *People's Mojahedin*, 680 F.3d at 837, then it is hard to see how unexplained delay outstripping the congressionally-imposed timeframe by a staggering 1200% (and counting) is not also egregious.

DEA's delay also indisputably "frustrates congressional intent." *Id.* Congress imposed the 90-deadline in section 823(i)(2) as a direct response to DEA's delays with respect to applications like SRI's. *See* Ex. 18 at A168-69 (explaining that purpose of amendment was to remedy "[i]nconsistency and *lengthy* review times at DEA" and to establish a "*transparent process*

for the applicant to determine the reasons for a delay in the application.") (emph. added). DEA's flat disregard of that mandate doesn't just *frustrate* Congress's purpose; it eviscerates it. This strongly favors mandamus. *See Cutler v. Hayes*, 818 F.2d 879, 897-98 (D.C. Cir. 1987) ("The court must also estimate the extent to which delay may be undermining the statutory scheme.").

Several other considerations confirm the unreasonableness of the delay. First, DEA interprets similar statutory deadlines under the CSA as requiring agency action by a date certain. Consider, for example, section 811(j), another 90-day deadline Congress added to the CSA with the 2015 Improving Regulatory Transparency for New Medical Therapies Act. 21 U.S.C. § 811(j). In language that mirrors section 823(i)(2)'s mandate, section 811(j) provides that when DEA receives notification from HHS that it has indexed a drug under section 572 of the Food Drug and Cosmetic Act, 21 U.S.C. § 360, "the Attorney General shall, not later than 90 days after the date described in paragraph (2), issue an interim final rule . . . ." 21 U.S.C. § 811(j)(1).

Less than a year after both sections 811(j)(1) and 823(i)(2) were added to the CSA, DEA had already issued an interim final rule within section 811(j)(1)'s 90-deadline. In that interim rule, DEA noted the

deadlines Congress had imposed in the 2015 amendment and interpreted the 90-day deadline in section 811(j)(1) as requiring it to act on HHS's recommendation "not later than 90 days" after the date described in section 811(j)(2). 81 Fed. Reg. 58,834, 58,835 (Aug. 26, 2016). "[I]dentical words used in different parts of the same statute are generally presumed to have the same meaning." *IBP, Inc. v. Alvarez*, 546 U.S. 21, 34 (2005). *See also Ne. Hosp. Corp. v. Sebelius*, 657 F.3d 1,11 (D.C. Cir. 2011) (same).

Here, the agency's disparate treatment of these twin deadlines is not reasonable. Indeed, though Congress gave DEA 90 days to complete the tasks required under sections 811(j)(1) and 823(i)(2), the agency's duty under the former requires substantially more resources than its duty under the latter. Unlike section 823(i)(2), which merely requires DEA to publish a two-page notice in the Federal Register, section 811(j)(1) requires the agency to "issue an interim final rule" controlling a drug. The August 26, 2016 interim final rule discussed above fills 15 pages of the Federal Register. DEA's ability to complete these complex administrative tasks in 90 days underscores the egregiousness of its failure to take simpler action here.

Second, other CSA provisions give DEA *less* time to do *more*. Section 823(i)(1), for example, gives DEA just 180 days to process, review, and decide whether to grant or issue an order show cause as to applications to

manufacture other controlled substances for use in clinical trials. 21 U.S.C. § 823(i)(1). If six months is a reasonable amount of time for DEA to process, review, and issue an initial decision with respect to similar applications, then it is more than enough time to do far less: notice SRI's application. Other examples abound.[4]

Third, DEA routinely notices applications to manufacture controlled substances, including cannabis, months after filing. *See* examples listed *supra* p. 17. And in a presentation DEA's Office of Diversion Control made in mid-April 2016—right around the time that it received SRI's application—the agency described its process for noticing applications in detail before warning that it *sometimes* "takes 4-6 *months* to complete." Ex. 3 at A083 (2016 DEA Presentation) (emph. added). Whether measured by the agency's past practice or its public statements, the delay at issue here is beyond the pale.

Fourth, DEA's extensive delays persist years after (1) Congress amended the statute to demand the very action DEA continues to withhold, (2) DEA told the public it desired applications like SRI's, *see* Ex. 16 (A158), and (3) DEA publicly acknowledged SRI's due process right to

[4] *E.g.*, 21 U.S.C. § 826(h)(1), § 826a, § 827(f)(1)-(3)(A).

consideration of its application, *id.* at A160 ("Any person who applies for a registration to grow marijuana . . . is entitled to due process in the consideration of the application by the Agency."). There is no excuse for DEA's refusal to act in this case. Nor is there any reason to believe it will act absent judicial intervention. Accordingly, the Court should not hesitate to exercise its equitable discretion.

b. DEA's unreasonable delay has caused and continues to cause extreme prejudice and concrete harm to health and human welfare.

The third and fifth *TRAC* factors, which assess the impact of the delay, strongly favor mandamus. 750 F.2d at 80. Under the third *TRAC* factor, courts recognize that delays that relate to health and welfare are more likely to necessitate judicial intervention than those that simply may have economic consequences. *Id.* Under the fifth *TRAC* factor, courts consider the nature and extent of the interests prejudiced by the agency's delay. *Id.* These factors are appropriately addressed together because the prejudice SRI suffers is co-extensive with the harm courts have found particularly suited for mandamus relief: harm to human health and welfare.

It was concern for human health and welfare that prompted Congress to add statutory deadlines to the CSA provisions requiring DEA to process applications to manufacture controlled substances for use in clinical trials.

The Committee Report on H.R. 639—the bill that would eventually become the "Improving Regulatory Transparency for New Medical Therapies Act"—explains that the deadlines were necessary "to facilitate patient access to new therapies in an efficient and transparent manner . . . ." Ex. 18 at A168-69; *see also* Ex. 19 at A164 (representative Pitts stating that deadlines were meant to "improve the transparency and consistency of the [DEA]'s . . . registration process for the manufacture of controlled substances for use in clinical trials" because doing so would "allow new and innovative treatments to get to patients who desperately need them"); *id.* ("This legislation was introduced . . . to provide a solution to delays experienced by patients in need."); *id.* ("Further, section 3 of this bill would bring much-needed certainty to another open-ended DEA process . . . manufacturers of controlled substances intended to be used in clinical trials for products not yet approved by the FDA."). Representative Pitts, Chairman of the House Subcommittee on Health of the Committee on Energy and Commerce explained:

> This bill also establishes a timeline for DEA to grant approval of manufacturers' applications to register controlled substances not yet approved by FDA to be used in clinical trials, allowing companies to properly plan clinical trial schedules for prospective new therapies. *This provision will get products to the market faster because innovators will be able to get clinical*

> *trials under way in a timely and predictable way, which is critical to drug developers and patients alike.*

Ex. 23 at A199 (hearing remarks) (emph. added).

DEA's ongoing delays on an issue so vital to public health have frustrated just about everyone. As one bipartisan group of Senators put it in their July 25, 2018 letter to then Attorney General Jeff Sessions: "Our nation's need for meaningful federally sanctioned research is critical" because "[r]esearch and medical communities should have access to research-grade materials to answer questions around marijuana's efficacy and potential impacts, both positive and adverse." Ex. 9 at A125. And just a week ago, a Second Circuit panel reviewing the propriety of classifying cannabis as a Schedule I substance emphasized that, in light of the "unusual health related circumstances" implicated by DEA's approach to cannabis regulation, "what has counted as appropriate speed in the past may not count as appropriate speed" anymore. *Washington v. Barr*, No. 18-859-CV, 2019 WL 2292194, at *8 (2d Cir. May 30, 2019).

Millions of Americans believe cannabis holds the key to ending their pain and suffering, making the need for clinical trials acute no matter the outcome of SRI's clinical trials. If those studies show that thirty-eight states (and counting), doctors, legislators, and the American public are all

wrong—i.e., that cannabis lacks medical utility—then we must know this now. Those using cannabis to treat conditions like PTSD may be jeopardizing their health and welfare. But in the more likely alternative—i.e., SRI's studies prove that cannabis has medical value—DEA's delay inexcusably deprives combat veterans and others of a treatment option necessary to ease their pain. Either way, more delay is unconscionable.

Simply put, the ongoing harm to human health from DEA's delay in this case is *certain*. As a result, any deference owed the agency is "sharply reduced." *See Cutler*, 818 F.2d at 898 ("The deference traditionally accorded an agency to develop its own schedule is sharply reduced when injury likely will result from avoidable delay.").

DEA's delay is also a disincentive to investors. As DEA has acknowledged, "[f]unding may actually be the most important factor in whether research with marijuana (or any other experimental drug) takes place." Ex. 16 at A158, n.2. But when DEA won't even process applications to obtain the materials to *begin* research, investors are less likely to support the research to completion. Where economic considerations implicate human health and welfare, this Court has favored compelling agency action. *See TRAC*, 750 F.2d at 86 (finding that the third *TRAC* factor weighed in favor of compelling agency action because of impact on health and human

welfare where the agency had delayed adjudicating claims for a form of unemployment assistance payments).

Zooming out brings other important concerns into focus. For example, it is no secret that, despite federal prohibition, medicinal cannabis is a growing billion-dollar industry at the state level; it might be the largest industry focused solely on transacting contraband since Prohibition. And with that comes profound economic consequences. The conflict between state and federal law is reason enough to compel the agency to act. DEA says the main obstacle preventing it from recognizing medicinal cannabis at the federal level is the lack clinical research. SRI is trying to solve that problem. But the agency won't act, making the problem worse, not better.

Were it just human health and welfare at stake, the case for mandamus would be quite compelling. But the convergence of health interests and important national interests behind SRI's application should remove any hesitation this Court may have.

c. No competing priority justifies DEA's delay.

DEA's unlawful delay has not been, and cannot be, justified by any need to attend to competing priorities. *TRAC*, 750 F.2d at 80. Because Congress expressly amended the CSA to add deadlines for clinical-research-based manufacture applications, it necessarily concluded that these

applications must be an agency priority. *See People's Mojahedin*, 680 F.3d at 837 (where command is specific and deadline to act imposed is relatively brief, Congress's intent that the agency act with dispatch is "manifest[]").

Moreover, just three months ago, the President issued an Executive Order on a National Roadmap to Empower Veterans and End Suicide declaring "we must do better in fulfilling our solemn obligation to care for all those who have served our country," that it "*is the policy of the United States* to end veteran suicide through the development of a comprehensive plan to empower veterans and end suicide through coordinated suicide prevention efforts, *prioritized research activities*, and strengthened collaboration across the public and private sectors," that "[a]nswering this call to action requires an aspirational, innovative, all-hands-on-deck approach to public health — *not government as usual*." Exec. Order No. 13,861, 84 Fed. Reg. 8,585 (Mar. 5, 2019) (emph. added). Noticing SRI's application would be a great start.

Where an agency offers no "'plea of administrative error, administrative convenience, practical difficulty in carrying out a legislative mandate, or need to prioritize in the face of limited resources,'" this factor favors mandamus. *In re Am. Rivers*, 372 F.3d at 420 (quoting *Cutler*, 818 F.2d at 898). DEA has never offered such a plea, and for good reason. It

cannot seriously argue drafting and publishing a two-page notice in the Federal Register would deplete agency resources. This is the epitome of perfunctory.

Accordingly, this *TRAC* factor also underscores the urgency of mandamus relief.

d. Agency impropriety is not a prerequisite for mandamus.

SRI does not concede the purity of DEA's motives,[5] but ultimately, the agency's intent is of little concern. The manifest egregiousness of its ongoing delay justifies mandamus even without ill intent. *See TRAC*, 750 F.2d at 80.

III. SRI has no adequate alternative remedy.

Mandamus is SRI's only path to relief. The "no adequate remedy" requirement is "'a condition designed to ensure that the writ will not be used as a substitute for the regular appeals process.'" *United States v. Jicarilla Apache Nation*, 564 U.S. 162, 206 n.11 (2011) (Ginsburg, J., concurring) (quoting *Cheney v. United States Dist. Ct. for D.C.*, 542 U.S.

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5 *See* Ex. 19 (A170) (article quoting official who said DOJ "effectively shut down [the] program to increase research registrations"); *cf. Washington*, 2019 WL 2292194, at *7 (May 30, 2019) (average delay in deciding petitions to reclassify drugs approximately nine years).

367, 380-81 (2004)). Mandamus is appropriate, however, when an agency's unreasonable delay threatens to thwart judicial review, making issuance of the writ necessary "to protect its future jurisdiction." *TRAC*, 750 F.2d at 76; *Gottlieb v. Pena*, 41 F.3d 730, 734 (D.C. Cir. 1994) ("[T]he proper recourse for a party aggrieved by delay that violates a statutory deadline is to apply for a court order compelling agency action.") (cites omitted).

Here, DEA's refusal to take even the simplest administrative step cuts off all other avenues of judicial review, thrusting SRI's application into administrative purgatory.

CONCLUSION

Petitioner SRI respectfully requests this Court issue a writ of mandamus compelling the Attorney General, DEA, or its Acting Administrator to issue a "notice of application" by 90 days from the date of service of this amended petition or fifteen days after the writ issues, whichever is later. Notably, mandamus here will not divest the agency of its discretion. It simply allows the process contemplated by the statute to begin, not end. The agency still maintains discretion to deny or delay the application, *see, e.g.*, 21 U.S.C. § 823(i)(2) (". . . the Attorney General shall register the applicant, *or serve an order to show cause* upon the applicant

in accordance with section 824(c) . . .”), should that continue to be its choice.

Dated June 11, 2019

Respectfully Submitted,

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CERTIFICATE OF COMPLIANCE

This Petition complies with the Federal Rule of Appellate Procedure 21(d) because it contains 7,773 words, excluding the accompanying documents required by Rule 21(a)(2)(C).

I further certify that this Petition complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6) because the Petition has been prepared in Georgia 14-point font for text and footnotes using Microsoft Word.

Dated June 11, 2019

/s/ Shane Pennington

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CERTIFICATE OF SERVICE

I certify that on June 11, 2019, I caused this amended petition, including all exhibits and addenda, to be served by U.S. postal mail and/or Federal Express on Respondents, as follows:

William P. Barr, Attorney General
United States Department of Justice
950 Pennsylvania Avenue NW
Washington, DC 20530

Uttam Dhillon, Acting Administrator
United States Drug Enforcement Administration
8701 Morrissette Drive
Springfield, VA 22152

United States Drug Enforcement Administration
8701 Morrissette Drive
Springfield, VA 22152

/s/ *Shane Pennington*
Shane Pennington

ADDENDA

Certificate as to Parties, Rulings, and Related Cases

Pursuant to D.C. Circuit Rules 21(d) and 28(a)(1), counsel for Petitioner states as follows:

A. Parties and Amici

SRI and Respondents William P. Barr, Uttam Dhillon, and DEA are the only parties to this matter. SRI is not aware of any amici who may appear.

B. Rulings Under Review

This is a corrected petition for a writ of mandamus to redress agency action unlawfully withheld and unreasonable delayed by DEA in noticing Petitioner's application. Accordingly, there is no agency or judicial decision under review.

C. Related Cases

Although there are no related cases that have been litigated in the district court, in this Court, or elsewhere, SRI may file a petition for review in this Court concurrent with this petition in a separate action soon after.

/s/ *Shane Pennington*
Shane Pennington

Dated: June 11, 2019

Corporate Disclosure Statement

In accordance with Federal Rule of Appellate Procedure 26.1 and D.C. Circuit Rule 26.1, Petitioner provides the following:

Scottsdale Research Institute, LLC states that it is an Arizona-based limited liability company under Arizona law. It is dedicated to advancing the state of medical care through rigorous research. Specifically, Petitioner aims to conduct high quality, controlled scientific studies intended to ascertain the general medical safety and efficacy of cannabis and cannabis products and examine various forms of cannabis administration. Petitioner has no parent corporation and no publicly held company owns a 10 percent or greater interest of its stock.

/s/ *Shane Pennington*
Shane Pennington

Dated: June 11, 2019

Statutory Addendum

KeyCite Yellow Flag - Negative Treatment
Proposed Legislation

United States Code Annotated
Title 21. Food and Drugs (Refs & Annos)
Chapter 13. Drug Abuse Prevention and Control (Refs & Annos)
Subchapter I. Control and Enforcement
Part C. Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances

21 U.S.C.A. § 823

§ 823. Registration requirements

Effective: October 24, 2018
Currentness

(a) Manufacturers of controlled substances in schedule I or II

The Attorney General shall register an applicant to manufacture controlled substances in schedule I or II if he determines that such registration is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes;

(2) compliance with applicable State and local law;

(3) promotion of technical advances in the art of manufacturing these substances and the development of new substances;

(4) prior conviction record of applicant under Federal and State laws relating to the manufacture, distribution, or dispensing of such substances;

(5) past experience in the manufacture of controlled substances, and the existence in the establishment of effective control against diversion; and

(6) such other factors as may be relevant to and consistent with the public health and safety.

(b) Distributors of controlled substances in schedule I or II

The Attorney General shall register an applicant to distribute a controlled substance in schedule I or II unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;

(2) compliance with applicable State and local law;

(3) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(4) past experience in the distribution of controlled substances; and

(5) such other factors as may be relevant to and consistent with the public health and safety.

(c) Limits of authorized activities

Registration granted under subsections (a) and (b) of this section shall not entitle a registrant to (1) manufacture or distribute controlled substances in schedule I or II other than those specified in the registration, or (2) manufacture any quantity of those controlled substances in excess of the quota assigned pursuant to section 826 of this title.

(d) Manufacturers of controlled substances in schedule III, IV, or V

The Attorney General shall register an applicant to manufacture controlled substances in schedule III, IV, or V, unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule III, IV, or V compounded therefrom into other than legitimate medical, scientific, or industrial channels;

(2) compliance with applicable State and local law;

(3) promotion of technical advances in the art of manufacturing these substances and the development of new substances;

(4) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(5) past experience in the manufacture, distribution, and dispensing of controlled substances, and the existence in the establishment of effective controls against diversion; and

(6) such other factors as may be relevant to and consistent with the public health and safety.

(e) Distributors of controlled substances in schedule III, IV, or V

The Attorney General shall register an applicant to distribute controlled substances in schedule III, IV, or V, unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;

(2) compliance with applicable State and local law;

(3) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(4) past experience in the distribution of controlled substances; and

(5) such other factors as may be relevant to and consistent with the public health and safety.

(f) Research by practitioners; pharmacies; research applications; construction of Article 7 of the Convention on Psychotropic Substances

The Attorney General shall register practitioners (including pharmacies, as distinguished from pharmacists) to dispense, or conduct research with, controlled substances in schedule II, III, IV, or V and shall modify the registrations of pharmacies so registered to authorize them to dispense controlled substances by means of the Internet, if the applicant is authorized to dispense, or conduct research with respect to, controlled substances under the laws of the State in which he practices. The Attorney General may deny an application for such registration or such modification of registration if the Attorney General determines that the issuance of such registration or modification would be inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.

Separate registration under this part for practitioners engaging in research with controlled substances in schedule II, III, IV, or V, who are already registered under this part in another capacity, shall not be required. Registration applications by practitioners wishing to conduct research with controlled substances in schedule I shall be referred to the Secretary, who shall determine the qualifications and competency of each practitioner requesting registration, as well as the merits of the research protocol. The Secretary, in determining the merits of each research protocol, shall consult with the Attorney General as to effective procedures to adequately safeguard against diversion of such controlled substances from legitimate medical or scientific use. Registration for the purpose of bona fide research with controlled substances in schedule I by a practitioner deemed qualified by the Secretary may be denied by the Attorney General only on a ground specified in section 824(a) of this title. Article 7 of the Convention on Psychotropic Substances shall not be construed to prohibit, or impose additional restrictions upon, research involving drugs or other substances scheduled under the convention which is conducted in conformity with this subsection and other applicable provisions of this subchapter.

(g) Practitioners dispensing narcotic drugs for narcotic treatment; annual registration; separate registration; qualifications; waiver

(1) Except as provided in paragraph (2), practitioners who dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment shall obtain annually a separate registration for that purpose. The Attorney General shall register an applicant to dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment (or both)

(A) if the applicant is a practitioner who is determined by the Secretary to be qualified (under standards established by the Secretary) to engage in the treatment with respect to which registration is sought;

(B) if the Attorney General determines that the applicant will comply with standards established by the Attorney General respecting (i) security of stocks of narcotic drugs for such treatment, and (ii) the maintenance of records (in accordance with section 827 of this title) on such drugs; and

(C) if the Secretary determines that the applicant will comply with standards established by the Secretary (after consultation with the Attorney General) respecting the quantities of narcotic drugs which may be provided for unsupervised use by individuals in such treatment.

(2)(A) Subject to subparagraphs (D) and (J), the requirements of paragraph (1) are waived in the case of the dispensing (including the prescribing), by a practitioner, of narcotic drugs in schedule III, IV, or V or combinations of such drugs if the practitioner meets the conditions specified in subparagraph (B) and the narcotic drugs or combinations of such drugs meet the conditions specified in subparagraph (C).

(B) For purposes of subparagraph (A), the conditions specified in this subparagraph with respect to a practitioner are that, before the initial dispensing of narcotic drugs in schedule III, IV, or V or combinations of such drugs to patients for maintenance or detoxification treatment, the practitioner submit to the Secretary a notification of the intent of

the practitioner to begin dispensing the drugs or combinations for such purpose, and that the notification contain the following certifications by the practitioner:

(i) The practitioner is a qualifying practitioner (as defined in subparagraph (G)).

(ii) With respect to patients to whom the practitioner will provide such drugs or combinations of drugs, the practitioner has the capacity to provide directly, by referral, or in such other manner as determined by the Secretary--

(I) all drugs approved by the Food and Drug Administration for the treatment of opioid use disorder, including for maintenance, detoxification, overdose reversal, and relapse prevention; and

(II) appropriate counseling and other appropriate ancillary services.

(iii)(I) The total number of such patients of the practitioner at any one time will not exceed the applicable number. Except as provided in subclause (II), the applicable number is 30.

(II) The applicable number is--

(aa) 100 if, not sooner than 1 year after the date on which the practitioner submitted the initial notification, the practitioner submits a second notification to the Secretary of the need and intent of the practitioner to treat up to 100 patients;

(bb) 100 if the practitioner holds additional credentialing, as defined in section 8.2 of title 42, Code of Federal Regulations (or successor regulations);

(cc) 100 if the practitioner provides medication-assisted treatment (MAT) using covered medications (as such terms are defined in section 8.2 of title 42, Code of Federal Regulations (or successor regulations)) in a qualified practice setting (as described in section 8.615 of title 42, Code of Federal Regulations (or successor regulations)); or

(dd) 275 if the practitioner meets the requirements specified in sections 8.610 through 8.655 of title 42, Code of Federal Regulations (or successor regulations).

(III) The Secretary may by regulation change such applicable number.

(IV) The Secretary may exclude from the applicable number patients to whom such drugs or combinations of drugs are directly administered by the qualifying practitioner in the office setting.

(C) For purposes of subparagraph (A), the conditions specified in this subparagraph with respect to narcotic drugs in schedule III, IV, or V or combinations of such drugs are as follows:

(i) The drugs or combinations of drugs have, under the Federal Food, Drug, and Cosmetic Act or section 262 of Title 42, been approved for use in maintenance or detoxification treatment.

(ii) The drugs or combinations of drugs have not been the subject of an adverse determination. For purposes of this clause, an adverse determination is a determination published in the Federal Register and made by the Secretary, after consultation with the Attorney General, that the use of the drugs or combinations of drugs for maintenance or detoxification treatment requires additional standards respecting the qualifications of practitioners to provide such treatment, or requires standards respecting the quantities of the drugs that may be provided for unsupervised use.

(D)(i) A waiver under subparagraph (A) with respect to a practitioner is not in effect unless (in addition to conditions under subparagraphs (B) and (C)) the following conditions are met:

(I) The notification under subparagraph (B) is in writing and states the name of the practitioner.

(II) The notification identifies the registration issued for the practitioner pursuant to subsection (f).

(III) If the practitioner is a member of a group practice, the notification states the names of the other practitioners in the practice and identifies the registrations issued for the other practitioners pursuant to subsection (f).

(ii) Upon receiving a determination from the Secretary under clause (iii) finding that a practitioner meets all requirements for a waiver under subparagraph (B), the Attorney General shall assign the practitioner involved an identification number under this paragraph for inclusion with the registration issued for the practitioner pursuant to subsection (f). The identification number so assigned shall be appropriate to preserve the confidentiality of patients for whom the practitioner has dispensed narcotic drugs under a waiver under subparagraph (A).

(iii) Not later than 45 days after the date on which the Secretary receives a notification under subparagraph (B), the Secretary shall make a determination of whether the practitioner involved meets all requirements for a waiver under subparagraph (B) and shall forward such determination to the Attorney General. If the Secretary fails to make such determination by the end of the such 45-day period, the Attorney General shall assign the practitioner an identification number described in clause (ii) at the end of such period.

(E)(i) If a practitioner is not registered under paragraph (1) and, in violation of the conditions specified in subparagraphs (B) through (D), dispenses narcotic drugs in schedule III, IV, or V or combinations of such drugs for maintenance treatment or detoxification treatment, the Attorney General may, for purposes of section 824(a)(4) of this title, consider the practitioner to have committed an act that renders the registration of the practitioner pursuant to subsection (f) to be inconsistent with the public interest.

(ii)(I) Upon the expiration of 45 days from the date on which the Secretary receives a notification under subparagraph (B), a practitioner who in good faith submits a notification under subparagraph (B) and reasonably believes that the conditions specified in subparagraphs (B) through (D) have been met shall, in dispensing narcotic drugs in schedule III, IV, or V or combinations of such drugs for maintenance treatment or detoxification treatment, be considered to have a waiver under subparagraph (A) until notified otherwise by the Secretary, except that such a practitioner may commence

to prescribe or dispense such narcotic drugs for such purposes prior to the expiration of such 45-day period if it facilitates the treatment of an individual patient and both the Secretary and the Attorney General are notified by the practitioner of the intent to commence prescribing or dispensing such narcotic drugs.

(II) For purposes of subclause (I), the publication in the Federal Register of an adverse determination by the Secretary pursuant to subparagraph (C)(ii) shall (with respect to the narcotic drug or combination involved) be considered to be a notification provided by the Secretary to practitioners, effective upon the expiration of the 30-day period beginning on the date on which the adverse determination is so published.

(F)(i) With respect to the dispensing of narcotic drugs in schedule III, IV, or V or combinations of such drugs to patients for maintenance or detoxification treatment, a practitioner may, in his or her discretion, dispense such drugs or combinations for such treatment under a registration under paragraph (1) or a waiver under subparagraph (A) (subject to meeting the applicable conditions).

(ii) This paragraph may not be construed as having any legal effect on the conditions for obtaining a registration under paragraph (1), including with respect to the number of patients who may be served under such a registration.

(G) For purposes of this paragraph:

(i) The term "group practice" has the meaning given such term in section 1395nn(h)(4) of Title 42.

(ii) The term "qualifying physician" means a physician who is licensed under State law and who meets one or more of the following conditions:

(I) The physician holds a board certification in addiction psychiatry or addiction medicine from the American Board of Medical Specialties.

(II) The physician holds an addiction certification or board certification from the American Society of Addiction Medicine or the American Board of Addiction Medicine.

(III) The physician holds a board certification in addiction medicine from the American Osteopathic Association.

(IV) The physician has, with respect to the treatment and management of opiate-dependent patients, completed not less than 8 hours of training (through classroom situations, seminars at professional society meetings, electronic communications, or otherwise) that is provided by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Psychiatric Association, or any other organization that the Secretary determines is appropriate for purposes of this subclause. Such training shall include--

(aa) opioid maintenance and detoxification;

(bb) appropriate clinical use of all drugs approved by the Food and Drug Administration for the treatment of opioid use disorder;

(cc) initial and periodic patient assessments (including substance use monitoring);

(dd) individualized treatment planning, overdose reversal, and relapse prevention;

(ee) counseling and recovery support services;

(ff) staffing roles and considerations;

(gg) diversion control; and

(hh) other best practices, as identified by the Secretary.

(V) The physician has participated as an investigator in one or more clinical trials leading to the approval of a narcotic drug in schedule III, IV, or V for maintenance or detoxification treatment, as demonstrated by a statement submitted to the Secretary by the sponsor of such approved drug.

(VI) The physician has such other training or experience as the State medical licensing board (of the State in which the physician will provide maintenance or detoxification treatment) considers to demonstrate the ability of the physician to treat and manage opiate-dependent patients.

(VII) The physician has such other training or experience as the Secretary considers to demonstrate the ability of the physician to treat and manage opiate-dependent patients. Any criteria of the Secretary under this subclause shall be established by regulation. Any such criteria are effective only for 3 years after the date on which the criteria are promulgated, but may be extended for such additional discrete 3-year periods as the Secretary considers appropriate for purposes of this subclause. Such an extension of criteria may only be effectuated through a statement published in the Federal Register by the Secretary during the 30-day period preceding the end of the 3-year period involved.

(VIII) The physician graduated in good standing from an accredited school of allopathic medicine or osteopathic medicine in the United States during the 5-year period immediately preceding the date on which the physician submits to the Secretary a written notification under subparagraph (B) and successfully completed a comprehensive allopathic or osteopathic medicine curriculum or accredited medical residency that--

(aa) included not less than 8 hours of training on treating and managing opioid-dependent patients; and

(bb) included, at a minimum--

(AA) the training described in items (aa) through (gg) of subclause (IV); and

(BB) training with respect to any other best practice the Secretary determines should be included in the curriculum, which may include training on pain management, including assessment and appropriate use of opioid and non-opioid alternatives.

(iii) The term "qualifying practitioner" means--

(I) a qualifying physician, as defined in clause (ii);

(II) a qualifying other practitioner, as defined in clause (iv), who is a nurse practitioner or physician assistant; or

(III) for the period beginning on October 1, 2018, and ending on October 1, 2023, a qualifying other practitioner, as defined in clause (iv), who is a clinical nurse specialist, certified registered nurse anesthetist, or certified nurse midwife.

(iv) The term "qualifying other practitioner" means a nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, or physician assistant who satisfies each of the following:

(I) The nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, or physician assistant is licensed under State law to prescribe schedule III, IV, or V medications for the treatment of pain.

(II) The nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, or physician assistant has--

(aa) completed not fewer than 24 hours of initial training addressing each of the topics listed in clause (ii)(IV) (through classroom situations, seminars at professional society meetings, electronic communications, or otherwise) provided by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Nurses Credentialing Center, the American Psychiatric Association, the American Association of Nurse Practitioners, the American Academy of Physician Assistants, or any other organization that the Secretary determines is appropriate for purposes of this subclause; or

(bb) has such other training or experience as the Secretary determines will demonstrate the ability of the nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, or physician assistant to treat and manage opiate-dependent patients.

(III) The nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, or physician assistant is supervised by, or works in collaboration with, a qualifying physician, if the nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, or physician assistant is

required by State law to prescribe medications for the treatment of opioid use disorder in collaboration with or under the supervision of a physician.

The Secretary may, by regulation, revise the requirements for being a qualifying other practitioner under this clause.

(H)(i) In consultation with the Administrator of the Drug Enforcement Administration, the Administrator of the Substance Abuse and Mental Health Services Administration, the Director of the National Institute on Drug Abuse, and the Commissioner of Food and Drugs, the Secretary shall issue regulations (through notice and comment rulemaking) or issue practice guidelines to address the following:

(I) Approval of additional credentialing bodies and the responsibilities of additional credentialing bodies.

(II) Additional exemptions from the requirements of this paragraph and any regulations under this paragraph.

(III) Such other elements of the requirements under this paragraph as the Secretary determines necessary for purposes of implementing such requirements.

Nothing in such regulations or practice guidelines may authorize any Federal official or employee to exercise supervision or control over the practice of medicine or the manner in which medical services are provided.

(ii) Not later than 18 months after the date of enactment of the Opioid Use Disorder Treatment Expansion and Modernization Act, the Secretary shall update the treatment improvement protocol containing best practice guidelines for the treatment of opioid-dependent patients in office-based settings. The Secretary shall update such protocol in consultation with experts in opioid use disorder research and treatment.

(I) Notwithstanding section 903 of this title, nothing in this paragraph shall be construed to preempt any State law that--

(i) permits a qualifying practitioner to dispense narcotic drugs in schedule III, IV, or V, or combinations of such drugs, for maintenance or detoxification treatment in accordance with this paragraph to a total number of patients that is more than 30 or less than the total number applicable to the qualifying practitioner under subparagraph (B)(iii)(II) if a State enacts a law modifying such total number and the Attorney General is notified by the State of such modification; or

(ii) requires a qualifying practitioner to comply with additional requirements relating to the dispensing of narcotic drugs in schedule III, IV, or V, or combinations of such drugs, including requirements relating to the practice setting in which the qualifying practitioner practices and education, training, and reporting requirements.

(J) Repealed. Pub.L. 114-198, Title III, § 303(b), July 22, 2016, 130 Stat. 723

(h) Applicants for distribution of list I chemicals

The Attorney General shall register an applicant to distribute a list I chemical unless the Attorney General determines that registration of the applicant is inconsistent with the public interest. Registration under this subsection shall not be required for the distribution of a drug product that is exempted under clause (iv) or (v) of section 802(39)(A) of this title. In determining the public interest for the purposes of this subsection, the Attorney General shall consider--

(1) maintenance by the applicant of effective controls against diversion of listed chemicals into other than legitimate channels;

(2) compliance by the applicant with applicable Federal, State, and local law;

(3) any prior conviction record of the applicant under Federal or State laws relating to controlled substances or to chemicals controlled under Federal or State law;

(4) any past experience of the applicant in the manufacture and distribution of chemicals; and

(5) such other factors as are relevant to and consistent with the public health and safety.

(i) Registration to manufacture certain controlled substances for use only in a clinical trial

(1) For purposes of registration to manufacture a controlled substance under subsection (d) for use only in a clinical trial, the Attorney General shall register the applicant, or serve an order to show cause upon the applicant in accordance with section 824(c) of this title, not later than 180 days after the date on which the application is accepted for filing.

(2) For purposes of registration to manufacture a controlled substance under subsection (a) for use only in a clinical trial, the Attorney General shall, in accordance with the regulations issued by the Attorney General, issue a notice of application not later than 90 days after the application is accepted for filing. Not later than 90 days after the date on which the period for comment pursuant to such notice ends, the Attorney General shall register the applicant, or serve an order to show cause upon the applicant in accordance with section 824(c) of this title, unless the Attorney General has granted a hearing on the application under section 958(i) of this title.

(j) Emergency medical services that administer controlled substances

(1) Registration

For the purpose of enabling emergency medical services professionals to administer controlled substances in schedule II, III, IV, or V to ultimate users receiving emergency medical services in accordance with the requirements of this subsection, the Attorney General--

(A) shall register an emergency medical services agency if the agency submits an application demonstrating it is authorized to conduct such activity under the laws of each State in which the agency practices; and

(B) may deny an application for such registration if the Attorney General determines that the issuance of such registration would be inconsistent with the requirements of this subsection or the public interest based on the factors listed in subsection (f).

(2) Option for single registration

In registering an emergency medical services agency pursuant to paragraph (1), the Attorney General shall allow such agency the option of a single registration in each State where the agency administers controlled substances in lieu of requiring a separate registration for each location of the emergency medical services agency.

(3) Hospital-based agency

If a hospital-based emergency medical services agency is registered under subsection (f), the agency may use the registration of the hospital to administer controlled substances in accordance with this subsection without being registered under this subsection.

(4) Administration outside physical presence of medical director or authorizing medical professional

Emergency medical services professionals of a registered emergency medical services agency may administer controlled substances in schedule II, III, IV, or V outside the physical presence of a medical director or authorizing medical professional in the course of providing emergency medical services if the administration is--

(A) authorized by the law of the State in which it occurs; and

(B) pursuant to--

(i) a standing order that is issued and adopted by one or more medical directors of the agency, including any such order that may be developed by a specific State authority; or

(ii) a verbal order that is--

(I) issued in accordance with a policy of the agency; and

(II) provided by a medical director or authorizing medical professional in response to a request by the emergency medical services professional with respect to a specific patient--

(aa) in the case of a mass casualty incident; or

(bb) to ensure the proper care and treatment of a specific patient.

(5) Delivery

A registered emergency medical services agency may deliver controlled substances from a registered location of the agency to an unregistered location of the agency only if the agency--

(A) designates the unregistered location for such delivery; and

(B) notifies the Attorney General at least 30 days prior to first delivering controlled substances to the unregistered location.

(6) Storage

A registered emergency medical services agency may store controlled substances--

(A) at a registered location of the agency;

(B) at any designated location of the agency or in an emergency services vehicle situated at a registered or designated location of the agency; or

(C) in an emergency medical services vehicle used by the agency that is--

(i) traveling from, or returning to, a registered or designated location of the agency in the course of responding to an emergency; or

(ii) otherwise actively in use by the agency under circumstances that provide for security of the controlled substances consistent with the requirements established by regulations of the Attorney General.

(7) No treatment as distribution

The delivery of controlled substances by a registered emergency medical services agency pursuant to this subsection shall not be treated as distribution for purposes of section 828 of this title.

(8) Restocking of emergency medical services vehicles at a hospital

Notwithstanding paragraph (13)(J), a registered emergency medical services agency may receive controlled substances from a hospital for purposes of restocking an emergency medical services vehicle following an emergency response, and without being subject to the requirements of section 828 of this title, provided all of the following conditions are satisfied:

(A) The registered or designated location of the agency where the vehicle is primarily situated maintains a record of such receipt in accordance with paragraph (9).

(B) The hospital maintains a record of such delivery to the agency in accordance with section 827 of this title.

(C) If the vehicle is primarily situated at a designated location, such location notifies the registered location of the agency within 72 hours of the vehicle receiving the controlled substances.

(9) Maintenance of records

(A) In general

A registered emergency medical services agency shall maintain records in accordance with subsections (a) and (b) of section 827 of this title of all controlled substances that are received, administered, or otherwise disposed of pursuant to the agency's registration, without regard to subsection 827(c)(1)(B) of this title.

(B) Requirements

Such records--

(i) shall include records of deliveries of controlled substances between all locations of the agency; and

(ii) shall be maintained, whether electronically or otherwise, at each registered and designated location of the agency where the controlled substances involved are received, administered, or otherwise disposed of.

(10) Other requirements

A registered emergency medical services agency, under the supervision of a medical director, shall be responsible for ensuring that--

(A) all emergency medical services professionals who administer controlled substances using the agency's registration act in accordance with the requirements of this subsection;

(B) the recordkeeping requirements of paragraph (9) are met with respect to a registered location and each designated location of the agency;

(C) the applicable physical security requirements established by regulation of the Attorney General are complied with wherever controlled substances are stored by the agency in accordance with paragraph (6); and

(D) the agency maintains, at a registered location of the agency, a record of the standing orders issued or adopted in accordance with paragraph (9).

(11) Regulations

The Attorney General may issue regulations--

(A) specifying, with regard to delivery of controlled substances under paragraph (5)--

(i) the types of locations that may be designated under such paragraph; and

(ii) the manner in which a notification under paragraph (5)(B) must be made;

(B) specifying, with regard to the storage of controlled substances under paragraph (6), the manner in which such substances must be stored at registered and designated locations, including in emergency medical service vehicles; and

(C) addressing the ability of hospitals, emergency medical services agencies, registered locations, and designated locations to deliver controlled substances to each other in the event of--

(i) shortages of such substances;

(ii) a public health emergency; or

(iii) a mass casualty event.

(12) Rule of construction

Nothing in this subsection shall be construed--

(A) to limit the authority vested in the Attorney General by other provisions of this subchapter to take measures to prevent diversion of controlled substances; or

(B) to override the authority of any State to regulate the provision of emergency medical services consistent with this subsection.

(13) Definitions

In this section:

(A) The term "authorizing medical professional" means an emergency or other physician, or another medical professional (including an advanced practice registered nurse or physician assistant)--

(i) who is registered under this chapter;

(ii) who is acting within the scope of the registration; and

(iii) whose scope of practice under a State license or certification includes the ability to provide verbal orders.

(B) The term "designated location" means a location designated by an emergency medical services agency under paragraph (5).

(C) The term "emergency medical services" means emergency medical response and emergency mobile medical services provided outside of a fixed medical facility.

(D) The term "emergency medical services agency" means an organization providing emergency medical services, including such an organization that--

(i) is governmental (including fire-based and hospital-based agencies), nongovernmental (including hospital-based agencies), private, or volunteer-based;

(ii) provides emergency medical services by ground, air, or otherwise; and

(iii) is authorized by the State in which the organization is providing such services to provide emergency medical care, including the administering of controlled substances, to members of the general public on an emergency basis.

(E) The term "emergency medical services professional" means a health care professional (including a nurse, paramedic, or emergency medical technician) licensed or certified by the State in which the professional practices and credentialed by a medical director of the respective emergency medical services agency to provide emergency medical services within the scope of the professional's State license or certification.

(F) The term "emergency medical services vehicle" means an ambulance, fire apparatus, supervisor truck, or other vehicle used by an emergency medical services agency for the purpose of providing or facilitating emergency medical care and transport or transporting controlled substances to and from the registered and designated locations.

(G) The term "hospital-based" means, with respect to an agency, owned or operated by a hospital.

(H) The term "medical director" means a physician who is registered under subsection (f) and provides medical oversight for an emergency medical services agency.

(I) The term "medical oversight" means supervision of the provision of medical care by an emergency medical services agency.

(J) The term "registered emergency medical services agency" means--

(i) an emergency medical services agency that is registered pursuant to this subsection; or

(ii) a hospital-based emergency medical services agency that is covered by the registration of the hospital under subsection (f).

(K) The term "registered location" means a location that appears on the certificate of registration issued to an emergency medical services agency under this subsection or subsection (f), which shall be where the agency receives controlled substances from distributors.

(L) The term "specific State authority" means a governmental agency or other such authority, including a regional oversight and coordinating body, that, pursuant to State law or regulation, develops clinical protocols regarding the delivery of emergency medical services in the geographic jurisdiction of such agency or authority within the State that may be adopted by medical directors.

(M) The term "standing order" means a written medical protocol in which a medical director determines in advance the medical criteria that must be met before administering controlled substances to individuals in need of emergency medical services.

(N) The term "verbal order" means an oral directive that is given through any method of communication including by radio or telephone, directly to an emergency medical services professional, to contemporaneously administer a controlled substance to individuals in need of emergency medical services outside the physical presence of the medical director or authorizing medical professional.

(k) "Factors as may be relevant to and consistent with the public health and safety" defined

In this section, the phrase "factors as may be relevant to and consistent with the public health and safety" means factors that are relevant to and consistent with the findings contained in section 801 of this title.

CREDIT(S)

(Pub.L. 91-513, Title II, § 303, Oct. 27, 1970, 84 Stat. 1253; Pub.L. 93-281, § 3, May 14, 1974, 88 Stat. 124; Pub.L. 95-633, Title I, § 109, Nov. 10, 1978, 92 Stat. 3773; Pub.L. 98-473, Title II, § 511, Oct. 12, 1984, 98 Stat. 2073; Pub.L. 103-200, § 3(c), Dec. 17, 1993, 107 Stat. 2336; Pub.L. 106-310, Div. B, Title XXXV, § 3502(a), Oct. 17, 2000, 114 Stat. 1222; Pub.L. 107-273, Div. B, Title II, § 2501, Nov. 2, 2002, 116 Stat. 1803; Pub.L. 109-56, § 1(a), (b), Aug. 2, 2005, 119 Stat. 591; Pub.L. 109-177, Title VII, § 712(a)(3), Mar. 9, 2006, 120 Stat. 263; Pub.L. 109-469, Title XI, § 1102, Dec. 29, 2006, 120 Stat. 3540; Pub.L. 110-425, § 3(b), Oct. 15, 2008, 122 Stat. 4824; Pub.L. 114-89, § 3, Nov. 25, 2015, 129 Stat. 701; Pub.L. 114-145, § 2(a)(1), Apr. 19, 2016, 130 Stat. 354; Pub.L. 114-198, Title III, § 303(a)(1), (b), July 22, 2016, 130

Stat. 720, 723; Pub.L. 115-83, § 2, Nov. 17, 2017, 131 Stat. 1267; Pub.L. 115-271, Title III, §§ 3201(a) to (d), 3202(a), Oct. 24, 2018, 132 Stat. 3943, 3944.)

Notes of Decisions (12)

21 U.S.C.A. § 823, 21 USCA § 823
Current through P.L. 116-19.

End of Document

Declaration of Suzanne Sisley, M.D.

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

In re Scottsdale Research Institute, LLC, *Petitioner*.	)	No. _____

DECLARATION OF SUZANNE SISLEY, M.D.

1. I am the President and Founder of Scottsdale Research Institute, LLC ("SRI"). I am also the Site Principal Investigator for SRI's FDA-approved clinical trial examining safety/efficacy of whole plant cannabis in combat veterans with treatment-resistant post-traumatic stress disorder ("PTSD"). I make this declaration based on my personal knowledge and in support of the Petition for a Writ of Mandamus.

2. SRI is an Arizona based limited liability company and clinical trials site dedicated to advancing the state of medical care through rigorous research. It is located at 5436 E Tapekim Rd., Cave Creek, AZ 85331 and our website is at http://www.sriresearch.org/. SRI strives to conduct high quality, controlled scientific studies to ascertain the general medical safety

and efficacy of cannabis products and examine forms of cannabis administration. SRI does not encourage recreational use of cannabis.

3. I am also a physician licensed to practice medicine in the State of Arizona and am in good standing. I completed my medical degree at the University of Arizona College of Medicine and did my residency at Good Samaritan Regional Medical Center in the fields of Internal Medicine and Psychiatry. I also served as Clinical Faculty at St. Joseph's Hospital and Medical Center at the MercyCare Adult Medicine Clinic for indigent patients.

4. I have received many honors and awards for my work, both in private practice and in research. For example, in 2001, I won the UA's Leo B. Hart Humanitarian Award from the University of Arizona College of Medicine. I also received the Arizona Medical Association's highest honor, the President's Distinguished Service Award.

5. I have received significant support from patient rights organizations including veteran groups around the country, such as the American Legion. In September 2016, the American Legion passed a resolution in support of our research, urging the DEA to license privately-

funded cannabis production to enable safe and efficient cannabis drug development.[1]

Private Practice

6. My primary care practice has always had a focus on treating veterans as well as underserved populations across Arizona.

7. More than a decade ago, I began noticing intractable PTSD and a suicide epidemic among veterans first-hand. PTSD is a mental health condition experienced by some who go through traumatic events. Symptoms vary from individual to individual. Common symptoms include anxiety, insomnia, depression, and nightmares. Currently there are limited approved pharmaceutical remedies for PTSD. Only two anti-depressants, sertraline (Zoloft) and paroxetine (Paxil), are approved by the FDA to treat PTSD.[2]

8. PTSD is quite prevalent among combat veteran populations. The association between combat exposure and PTSD is established. Measured rates of PTSD among combat veterans consistently exceeds 10%.[3] For example, according to a RAND study published on the VA website, the

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[1] See https://archive.legion.org/bitstream/handle/20.500.12203/5763/2016N011.pdf. See also B. Bender, American Legion to Trump: Allow marijuana research for vets, Politico (May 20, 2017).

[2] See https://www.youtube.com/watch?v=Idujb84MwPE ("Weed 3") at 3:30 (April 19, 2015).

[3] See Hines, L. A., Sundin, J., Rona, R. J., Wessely, S., & Fear, N. T. (2014). Posttraumatic stress disorder post Iraq and Afghanistan: prevalence among military subgroups. Canadian journal of psychiatry. Revue canadienne de psychiatrie, 59(9), 468–479. doi:10.1177/070674371405900903

prevalence of PTSD in Operation Enduring Freedom and Operation Iraqi Freedom was 13.8% out of 1,938 participants. Another study found that prevalence rates for PTSD or depression with serious functional impairment ranged between 8.5% and 14.0%.[4] PTSD is one of the most common psychiatric diagnosis among veterans using the VA hospitals.[5]

9. Suicide rates are also quite high among veteran population. The VA estimates that around 20 veterans per day take their own lives.[6]

10. Many of my veteran clients with PTSD did not respond to conventional medications. Some clients told me that using cannabis helped alleviate their symptoms.[7] For many, cannabis was the only drug that worked, reversing insomnia or easing depression and anxiety. Patients told me that cannabis effectively quelled nightmares, flashbacks, and hypervigilance.

11. This first-hand experience inspired me to conduct clinical trials on the safety and efficacy of cannabis use to suppress treatment resistant

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4 See https://www.ptsd.va.gov/professional/treat/essentials/epidemiology.asp.

5 Ralevski, E., Olivera-Figueroa, L. A., & Petrakis, I. (2014). PTSD and comorbid AUD: a review of pharmacological and alternative treatment options. Substance abuse and rehabilitation, 5, 25–36. doi:10.2147/SAR.S37399.

6 See https://www.mentalhealth.va.gov/docs/2016suicidedatareport.pdf at 22.

7 See Weed 3 at 5:00.

PTSD, which I discussed in CNN's "Weed 3: The Marijuana Revolution,"[8] an April 19, 2015 special report by CNN's chief medical correspondent Dr. Sanjay Gupta. This documentary not only explains in detail how veterans that struggle with PTSD have come to rely on cannabis, but also how we overcame numerous obstacles to be able to do our research, which I discuss below.

The Road to Clinical Trials

12. I struggled for seven years to get approval from four different federal agencies to conduct clinical trials of cannabis as a treatment for PTSD symptoms in veterans.

13. In 2009, I began collaborating with the Multidisciplinary Association for Psychedelic Studies (MAPS) on a proposal for the FDA. On Nov. 11, 2010, MAPS' clinical research team submitted our protocol to the FDA, and FDA approval came in April 2011.

14. On July 30, 2012, we submitted the protocol to the University of Arizona Institutional Review Board (IRB), which approved the study in October 2012.

[8] Although the video does not appear to be available from CNN, the video is widely available online, for example on YouTube at https://www.youtube.com/watch?v=Idujb84MwPE. I am introduced in the video at 3:30, and our struggle to obtain all the necessary government permissions begins at 5:30.

15. Shortly after FDA approval, we sent the proposal to NIDA and PHS for approval. After a series of rejections, we finally obtained approval from these agencies around March 2014. That approval was critical because it allowed us to be able to purchase federally legal cannabis from NIDA, the only source of cannabis legal for use in federally regulated research.

16. On April 17, 2014, NIDA informed us that it did not have the cannabis we needed for our study. Shortly after that, NIDA told us that it would have to grow the cannabis we needed for our protocol.

17. In June 2014, I was released by the University of Arizona. They chose not to renew my contract of employment and two other subcontracts. My assistant professorship was terminated. As a result, I lost my healthcare, primary income, and pension. And without an academic appointment, I was unable to continue my research with the university. I discussed this in an interview with CNN's Sanjay Gupta in July 2014.[9]

18. On November 2, 2015, we submitted our protocol to the DEA. As part of the approval process, the DEA inspected SRI. In April 2016, the DEA approved my Schedule I license to do research with cannabis, which is still active. That license removed the last barrier to the study.

[9] The interview is available at https://www.cnn.com/2014/07/12/health/marijuana-researcher-arizona/index.html.

19. Our phase II clinical trials titled "Placebo-Controlled, Triple-Blind, Randomized Crossover Pilot Study of the Safety and Efficacy of Four Different Potencies of Smoked Marijuana in 76 Veterans with Chronic, Treatment-Resistant Posttraumatic Stress Disorder (PTSD)" began in early 2017, and we concluded it in early 2019. SRI treated 76 participants as part of the study. MAPS sponsored the study and it was funded with a $2.1 million grant from the Colorado Department of Public Health and Environment. The study's protocol is available online.[10] We are aiming to publish our results in late 2019. The data looks promising, and justifies further examination with an alternative supply of high-quality natural cannabis flower.

NIDA Cannabis

20. On August 10, 2016, NIDA approved SRI's request to order 6.3kg of cannabis for our clinical trials. We had requested multiple cannabis strains with varying levels of THC and CBD, including high THC, high CBD, balanced THC/CBD, and placebo. On August 25, 2016, I received the first shipment. The cannabis arrived frozen, in dried bulk form. SRI tested the cannabis at a DEA-licensed laboratory.

21. Generally speaking, the NIDA cannabis SRI received looked nothing like commercial grade medical cannabis one can buy from

[10] See https://www.sriresearch.org/MJP1-A6V1-FINAL-16MAR2017-Web%20(1).html.

dispensaries states where medicinal cannabis is legal. NIDA cannabis consistently appears to have extraneous material like sticks, stems, and seeds. Many packages looked like the green powder shown below from a 2017 article on pbs.org that I am quoted in:[11]

22. I am also quoted in a 2017 Washington Post article titled "Government marijuana looks nothing like the real stuff. See for yourself," where a side by side comparison of commercial medicinal cannabis and NIDA cannabis can be seen:[12]

[11] See C. Hellerman "Scientists say the government's only pot farm has moldy samples — and no federal testing standards," PBS (Mar. 8, 2017) (https://www.pbs.org/newshour/nation/scientists-say-governments-pot-farm-moldy-samples-no-guidelines). I took this picture.

[12] See C. Ingraham and T. Chappell, "Government marijuana looks nothing like the real stuff. See for yourself," Washington Post (Mar. 13, 2017) (https://www.washingtonpost.com/news/wonk/wp/2017/03/13/government-marijuana-looks-nothing-like-the-real-stuff-see-for-yourself/?utm_term=.2dcae33401d3/).

23. In my opinion, both as a researcher and physician, the quality of this cannabis had an adverse impact on the study results and sometimes on the study subjects. For example, I noticed that bronchial irritation was a common complaint among the study subjects. I believe this side effect could have been mitigated if not eliminated had SRI been able to grow and use its own cannabis (which would have only contained the flowering tops of the plant without the extraneous plant material that can burn more harshly and cause excessive mucosal irritation) or simply if SRI could have used other cannabis that did not have extraneous material and excessively high levels of mold.

24. Before I could use the study drug, I had to sign a Release and Indemnity Agreement and take full responsibility for the preparation and

distribution of the government's cannabis. Physicians and principal investigators should not be put into a position where we must knowingly distribute cannabis flower to enrolled study subjects, while then being forced to accept full liability for this suboptimal study drug.

25. NIDA cannabis was not only inadequate for the Phase II trial we just completed, but will be inadequate for further studies, such as Phase III clinical trials or other Phase II clinical trials. The presence of sticks, stems, and seeds and significant mold makes this drug unsuitable for clinical research in certain patient populations.

26. Because NIDA cannabis is inadequate, SRI is now looking to import cannabis from a Canadian company for other projects, such as clinical trials to test the safety and efficacy of cannabis versus fentanyl for management of breakthrough pain in terminal cancer patients.

Application to DEA

27. On October 1, 2016, I submitted SRI's application for registration under the Controlled Substances Act. I submitted answers to supplemental questionnaire to DEA shortly after.

28. In the supplemental questionnaire, I told DEA that SRI was conducting an FDA approved Phase 2 randomized controlled trial evaluating the safety and efficacy of cannabis for military veterans with PTSD, that SRI

planned to move into Phase 3 trials in next 3 years, and that it would need a supply of cannabis other than from NIDA. The purpose of SRI's application was to allow it to cultivate cannabis that could be used for Phase 3 FDA trials. The only way cannabis could ever be approved as an FDA prescription medicine is through Phase 3 trials.

29. I explained that once SRI was licensed, it would supply its own internal, FDA sanctioned and licensed clinical trials. I also discussed supplying academic and private researchers across the country to provide them with a consistent supply of medical product for clinical trials. I did not list anybody else as prospective customers because I am unaware of any other researchers allowed to do clinical trials involving cannabis.

30. Since I filed SRI's application more than two-and-a-half years ago, I have followed up with the DEA numerous times. I believe I called DEA five times between June 2017 to August 2018. I also exchanged e-mails with the agency on June 22, 2017, but after a follow up e-mail on July 15, 2017, I did not hear back from the agency.

31. One year later, I followed up on my application again in an August 30, 2018 e-mail, writing:

> I have contacted my local DEA office regularly asking them the status of our application over the past two years and continue to get a vague response saying they have no idea when the application will ever be processed.

> Can you provide us another update from the national office on when the applications will be evaluated?
>
> I know we've discussed this on the phone several times over the last few years and I continue to hear from you that you are unsure of when this application above will be assessed. So given the continual uncertainty from your office, I've stopped inquiring with national office because this seemed futile.

In response, I was only told that the status of SRI's application remained the same.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on _5_, June 2019.

Suzanne Sisley, M.D.
President of Petitioner SRI, LLC

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EXHIBIT 1

Form-225

APPLICATION FOR REGISTRATION
Under the Controlled Substances Act

APPROVED OMB NO 1117-0012
FORM DEA-225 (04-12)
FORM EXPIRES: 7/31/2018

INSTRUCTIONS

Save time - apply on-line at *www.deadiversion.usdoj.gov*

1. To apply by mail complete this application. Keep a copy for your records.
2. Mail this form to the address provided in Section 7 or use enclosed envelope.
3. The "MAIL-TO ADDRESS" can be different than your "PLACE OF BUSINESS" address.
4. If you have any questions call 800-882-9539 prior to submitting your application.

IMPORTANT: DO NOT SEND THIS APPLICATION AND APPLY ON-LINE

DEA OFFICIAL USE:

Do you have other DEA registration numbers?
☐ NO ☐ YES

MAIL-TO ADDRESS Please print mailing address changes to the right of the address in this box.

FEE FOR ONE (1) YEAR - see Section 2
FEE IS NON-REFUNDABLE

SECTION 1 APPLICANT IDENTIFICATION

☐ Individual Registration ☒ Business Registration

Name 1 (Last Name of individual - OR- Business or Facility Name)
Scottsdale Research Institute

Name 2 (First Name and Middle Name of individual - OR- Continuation of business name)

PLACE OF BUSINESS Street Address Line 1
1225 W Deer Valley Rd

PLACE OF BUSINESS Address Line 2

City
PHOENIX

State AZ Zip Code 85027

Business Phone Number
480 922-9015

Point of Contact
Suzanne Sisley, MD

Business Fax Number
866 933-6787

Email Address
suesisley@aol.com

DEBT COLLECTION INFORMATION Mandatory pursuant to Debt Collection Improvements Act

Tax Identification Number (*if registration is for business*)
47-2660788

Provide TIN or SSN. See additional information note #3 on page 4.

Social Security Number (*if registration is for individual*)

SECTION 2

BUSINESS ACTIVITY

Check one business activity box only

Researcher - See page 4 for required attachments

☐ Analytical Lab.....fee for one year is $244
☐ Researcher w/Sched I.....fee for one year is $244
☐ Researcher w/Sched II - V.....fee for one year is $244
☐ Canine Handler.....fee for one year is $244
☐ Distributor.....fee for one year is $1523
☐ Exporter.....fee for one year is $1523
☐ Importer.....fee for one year is $1523
☐ Reverse Distributor.....fee for one year is $1523
☐ Manufacturer.....fee for one year is $3047
☒ Manufacturer BULK.....fee for one year is $3047

SECTION 3

A. DRUG SCHEDULES Check all that apply

Enter drug codes on page 2.

☒ List 1 (L1) - manufacturers & importers ONLY ☐ Schedule 2 Narcotic ☐ Schedule 3 Narcotic ☐ Schedule 4
☐ Schedule 1 ☐ Schedule 2 Non-Narcotic (2N) ☐ Schedule 3 Non-Narcotic (3N) ☐ Schedule 5

☐ Check this box if you require official order forms - for purchase of schedule 2 controlled substances.

B. MANUFACTURERS ONLY Mark each box with an X to indicate which drug schedule is handled for each manufacturing stage

☒ STAGE 1 Bulk synthesis/extraction	☐ 1	☐ 2 Narcotic	☐ 2 Non-Narcotic	☐ 3 Narcotic	☐ 3 Non-Narcotic	☐ 4	☐ 5	☒ STAGE 3 Package / Repackage Label / Relabel	☐ 1	☐ 2 Narcotic	☐ 2 Non-Narcotic	☐ 3 Narcotic	☐ 3 Non-Narcotic	☐ 4	☐ 5
☒ STAGE 2 Dosage form manufacture	☐ 1	☐ 2 Narcotic	☐ 2 Non-Narcotic	☐ 3 Narcotic	☐ 3 Non-Narcotic	☐ 4	☐ 5	☒ STAGE 4 Non-human consumption	☐ 1	☐ 2 Narcotic	☐ 2 Non-Narcotic	☐ 3 Narcotic	☐ 3 Non-Narcotic	☐ 4	☐ 5

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SECTION 4

STATE LICENSE(S)

You MUST be currently authorized to prescribe, distribute, dispense, conduct research, or otherwise handle the controlled substances in the schedules for which you are applying under the laws of the state or jurisdiction in which you are operating or propose to operate.

Be sure to include both state license numbers if applicable

* see attached letter

State License Number (REQUIRED)

Expiration Date (REQUIRED) / / MM - DD - YYYY

What state issued this license ? _____

State Controlled Substances License Number (if required)

Expiration Date (if required) / / MM - DD - YYYY

What state issued this license ? _____

SECTION 5

LIABILITY

IMPORTANT

All questions in this section must be answered.

1. Has the applicant ever been convicted of a crime in connection with controlled substance(s) under state or federal law, or been excluded or directed to be excluded from participation in a medicare or state health care program, or is any such action pending? YES ☐ NO ☒

Date(s) of incident MM-DD-YYYY: ☐☐-☐☐-☐☐☐☐

2. Has the applicant ever surrendered (for cause) or had a federal controlled substance registration revoked, suspended, restricted, or denied, or is any such action pending? YES ☐ NO ☒

Date(s) of incident MM-DD-YYYY: ☐☐-☐☐-☐☐☐☐

3. Has the applicant ever surrendered (for cause) or had a state professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation, or is any such action pending? YES ☐ NO ☒

Date(s) of incident MM-DD-YYYY: ☐☐-☐☐-☐☐☐☐

4. If the applicant is a corporation (other than a corporation whose stock is owned and traded by the public), association, partnership, or pharmacy, has any officer, partner, stockholder, or proprietor been convicted of a crime in connection with controlled substance(s) under state or federal law, or ever surrendered, for cause, or had a federal controlled substance registration revoked, suspended, restricted, denied, or ever had a state professional license or controlled substance registration revoked, suspended, denied, restricted or placed on probation, or is any such action pending? YES ☐ NO ☒

Date(s) of incident MM-DD-YYYY: ☐☐-☐☐-☐☐☐☐

Note: If question 4 does not apply to you, be sure to mark 'NO'. It will slow down processing of your application if you leave it blank.

EXPLANATION OF "YES" ANSWERS

Applicants who have answered "YES" to any of the four questions above must provide a statement to explain each "YES" answer.

Use this space or attach a separate sheet and return with application

Liability (question # _____ Location(s) of incident _____

Nature of incident:

Disposition of incident:

SECTION 6 EXEMPTION FROM APPLICATION FEE

☐ Check this box if the applicant is a federal, state, or local government official or institution. Does not apply to contractor-operated institutions.

Business or Facility Name of Fee Exempt Institution. Be sure to enter the address of this exempt institution in Section 1.

The undersigned hereby certifies that the applicant named hereon is a federal, state or local government official or institution, and is exempt from payment of the application fee

FEE EXEMPT CERTIFIER

Signature of certifying official (other than applicant) _____ Date _____

Provide the name and phone number of the certifying official

Print or type name and title of certifying official _____ Telephone No. (required for verification) _____

SECTION 7

METHOD OF PAYMENT

Check one form of payment only

☐ Check Make check payable to: Drug Enforcement Administration See page 4 of instructions for important information.

☒ American Express ☐ Discover ☐ Master Card ☐ Visa

Credit Card Number ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐ Expiration Date ☐☐ - ☐☐

Sign if paying by credit card

Signature of Card Holder _____

Printed Name of Card Holder _____

Mail this form with payment to:

DEA Headquarters
ATTN: Registration Section/ODR
P.O. Box 2639
Springfield, VA 22152-2639

FEE IS NON-REFUNDABLE

SECTION 8

APPLICANT'S SIGNATURE

Sign in ink

I certify that the foregoing information furnished on this application is true and correct.

Signature of applicant (sign in ink) _____ Date 10-1-2016

Suzanne Sisley, MD - President, SRI

Print or type name and title of applicant

WARNING: 21 USC 843(d), states that any person who knowingly or intentionally furnishes false or fraudulent information in the application is subject to a term of imprisonment of not more than 4 years, and a fine under Title 18 of not more than $250,000, or both.

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C. SCHEDULE AND DRUG CODES

Listed below are examples of schedules 1-5 and List 1 codes. Check all drug codes you handle as required.
For more information, see our website at *www.deadiversion.usdoj.gov*, 21 CFR 1308, or call *1-800-882-9539*.

Canine Handler	must mark schedule 1	**Distributor**	must mark all schedule 1, drug code 2012
Exporter	must mark all schedule 1-5	**Reverse Distributor**	must mark all schedule 1, drug code 2012
Importer	must mark all schedule 1-5 & List 1 codes	**Researcher w/Sched 1**	must mark schedule 1
Manufacturer	must mark all schedule 1, 2 & List 1 codes	**Researcher w/Sched 2-5**	must mark schedule 2 to be manufactured or imported as part of research

If you bulk manufacture a substance, check the 'BULK?' column after the applicable class code.

SCHEDULE 1 NARCOTIC & NON-NARCOTIC	CODE	BULK?
3,4-Methylenedioxyamphetamine (MDA)	7400	
3,4-Methylenedioxymethamphetamine (MDMA)	7405	
4-Methyl - 2,5 - Dimethoxyamphetamine (DOM, STP)	7395	
4-Methylaminorex (cis isomer) (U4Euh, McN-422)	1590	
Alphacetylmethadol (except LAAM)	9603	
Bufotenine (Mappine)	7433	
Marihuana / Cannabidiol	7360/7372	X
Diethyltryptamine (DET) (	7434	
Difenoxin 1MG/25UG AtSO4 /DU (Motofen)	9167	
Dimethyltryptamine (DMT)	7435	
Etorphine (except HCL)	9056	
Gamma Hydroxybutyric Acid (GHB)	2010	
Heroin (Diamorphine)	9200	
Ibogaine	7260	
Lysergic acid diethylamide (LSD)	7315	
Mescaline	7381	
Marihuana	7360	X
Methaqualone (Quaalude)	2565	
Normorphine	9313	
Peyote	7415	
Psilocybin	7437	
Tetrahydrocannabinols (THC)	7370	X

SCHEDULE 3 NARCOTIC & NON-NARCOTIC	CODE	BULK?
Anabolic Steroids	4000	
Barbituric acid derivative	2100	
Benzphetamine (Didrex, Inspetyl)	1228	
Buprenorphine (Buprenex, Temgesic)	9064	
Butabarbital	2100/2175	
Butalbital	2100/2165	
Codeine combo product (Empirin)	9804	
Dihydrocodeine combo product (Compal)	9807	
Dronabinol in sesame oil soft cap (Marinol)	7369	
Gamma-Hydroxybutyric Acid preparations (Zyrem)	2012	
Hydrocodone combo products (Lorcet, Vicodin)	9806	
Ketamine (Ketaset, Ketalar)	7285	
Morphine combo product	9810	
Nalorphine (Nalline)	9400	
Opium combo product (Paregoric)	9809	
Pentobarbital suppository dosage (FP3)	2270	
Phendimetrazine (Plegine, Bontril)	1615	
Thiopental	2100/2329	

SCHEDULE 5 NARCOTIC & NON-NARCOTIC	CODE	BULK?
Codeine preparations (Robitussin A-C, Pediacof)	9050	
Pyrovalerone (Centroton, Thymergix)	1485	

SCHEDULE 2 NARCOTIC & NON-NARCOTIC	CODE	BULK?
Amobarbital (Amytal, Tuinal)	2125	
Amphetamine (Dexedrine, Adderall)	1100	
Cocaine (Methyl benzoylecgonine)	9041	
Codeine (Morphine methyl ester)	9050	
Dextropropoxyphene (bulk)	9273	
Diphenoxylate	9170	
Fentanyl (Duragesic)	9801	
Hydrocodone (Dihydrocodeinone)	9193	
Hydromorphone (Dilaudid)	9150	
Levo-Alphacetylmethadol (LAAM)	9648	
Levorphanol (Levo-Dromoran)	9220	
Meperidine (Demerol, Mepergan)	9230	
Methadone (Dolophine, Methadose)	9250	
Methamphetamine (Desoxyn)	1105	
Methylphenidate (Concerta, Ritalin)	1724	
Morphine (MS Contin, Roxanol)	9300	
Opium, powdered	9639	
Oxycodone (Oxycontin, Percocet)	9143	
Oxymorphone (Numorphan)	9652	
Pentobarbital (bulk) (Nembutal)	2270	
Phencyclidine (PCP)	7471	
Secobarbital (Seconal, Tuinal)	2315	

SCHEDULE 4 NARCOTIC & NON-NARCOTIC	CODE	BULK?
Alprazolam (Xanax	2882	
Barbital (Veronal, Plexonal)	2145	
Chloral Hydrate (Noctec)	2465	
Chlordiazepoxide (Librium)	2744	
Clonazepam (Klonopin)	2737	
Clorazepate (Tranxene)	2768	
Diazepam (Valium)	2765	
Flurazepam (Dalmane)	2767	
Lorazepam (Ativan)	2885	
Meprobamate (Miltown, Equanil)	2820	
Midazolam (Versed)	2884	
Oxazepam (Serax, Serenid-D)	2835	
Phenobarbital (Pastin, Zantryl)	2285	
Phentermine	1640	
Temazepam (Restoril)	2925	
Zolpidem (Ambien, Stilnox)	2783	

LIST 1 REGULATED CHEMICALS ** ONLY manufacturers & importers may select List 1	CODE	BULK?
Ephedrine	8113	
Phenylpropanolamine	1225	
Pseudoephedrine	8112	

WRITE IN ADDITIONAL CODES You may write in additional drug codes in this section. Attach a separate sheet if needed.

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EXHIBIT 2

TABLE OF CONTENTS: APPLICATION BULK MANUFACTURE SCHEDULE I & II CONTROLLED SUBSTANCES

U.S. DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
BULK MANUFACTURER QUESTIONS
SCHEDULE I & II CONTROLLED SUBSTANCES

Company Name: **Scottsdale Research Institute SRI**

Attention Applicant or Registrant:

In order to process your company's request to bulk manufacture Schedule I and II controlled substances, the Regulatory Unit (DRGR) must obtain the information requested in this questionnaire. (PLEASE FILL OUT THIS FORM IN ITS ENTIRETY).

THIS QUESTIONNAIRE IS BEING SUBMITTED BY THE FOLLOWING:

NAME OF PERSON SUBMITTING: Dr. Suzanne Sisley MD _____
(PLEASE PRINT)

SIGNATURE OF PERSON SUBMITTING: _____
(PLEASE SIGN)

TITLE OF PERSON: President and Principal Investigator

NAME OF COMPANY: Scottsdale Research Institute SRI

DEA REGISTRATION NUMBER (See attached pages 34 & 35):
schedule 1: RS0496225
schedule 2–5: BS5887255

APPLICATION CONTROL NUMBER: H16068002E

TELEPHONE NUMBER: (480) 326-6023_____

E-MAIL ADDRESS: ssisleymd@gmail.com or suesisley@aol.com

WEBSITE: none _____

FAX NUMBER: (866) 933-6787

DATE OF SUBMISSION: 1-24-2017

THE INFORMATION IN THIS DOCUMENT IS CERTIFIED AS ACCURATE AND CURRENT AS OF:

(SIGNATURE)  (DATE):_____ **12-17-2016**___

1

U.S. DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
BULK MANUFACTURER QUESTIONS
SCHEDULE I & II CONTROLLED SUBSTANCES

Company Name: **Scottsdale Research Institute SRI**
The following questions pertain to your company's request to bulk manufacture Schedule I and/or II controlled substances. Please provide detailed responses to the following questions for <u>each</u> drug code that your company has proposed to manufacture in bulk.

1. **What is the purpose for the bulk manufacture of the controlled substance?**

The purpose for the bulk manufacture of the controlled substance is to provide appropriately licensed DEA purchasers with a high grade, accurately tested supply of Cannabis sativa L. Cannabis is a complex plant with the potential to provide multiple medical breakthroughs. Through the consistent supply of medical grade cannabis that complies to a tightly defined set of chemical profiles, this facility will supply a highly standardized library of cannabis phenotypes from which researchers can more accurately perform their work.

2. **Specifically, from start to finish, describe the production process, for each controlled substance.**

Scottsdale Research Institute SRI will utilize *Cannabis sativa* L. seeds, including marijuana and hemp cultivars, imported from one of the attached federally legal foreign suppliers who will be functioning only under approved permit from the US Drug Enforcement Administration (DEA). Plants will be grown in hydroponic media (Grodan) with an automated water exchange system, commercial nutrient solutions (General Hydroponics, Sebastopol, CA, USA) and combination of LED & high-pressure sodium vapor lighting.

An initial 4 wks. of vegetative growth conditions will be employed an 18 : 6 h, light : dark regime and high-N nutrient solution.

During vegetative growth, the sex of individual plants will be determined using a male-linked sequence characterized amplified region (SCAR) marker (Mandolino *et al.*, 1999). Staminate and pistillate plants will be subsequently maintained in separate growth chambers during 10–12 wks. of flowering conditions using a 12 : 12 h, light : dark regime and high phosphorus (P) nutrient solution.

Full-sib inbreeding will be performed in each line for multiple generations to reduce heterozygosis. Each generation, the male cohort will be thinned to a single plant before anthesis. Pollen will be applied by hand to flowers of a single female plant over several weeks of successive flowering and subsequent generations will be established from the resulting seed. This process will be repeated multiple times to produce near-isogenic lines that serve as parents in a hybrid cross between the various drug genotype cultivars.

THE INFORMATION IN THIS DOCUMENT IS CERTIFIED AS ACCURATE
AND CURRENT AS OF:

(SIGNATUR]  (DATE):_____ **12-17-2016**___

U.S. DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
BULK MANUFACTURER QUESTIONS
SCHEDULE I & II CONTROLLED SUBSTANCES

Company Name: **Scottsdale Research Institute SRI**

Plants will be grown for 4 weeks under vegetative conditions and subjected to flowering conditions for an additional 8 weeks. After 12 wks. of growth, plants will be harvested and dried for quantitative analysis of cannabinoids in female inflorescences. Residual plant material will be disposed of according to a DEA-approved procedure, and all drug accountability logs will be continuously updated to ensure rigorous accuracy and compliance.

3. What materials will be used to manufacture the controlled substance(s) and in what quantities?

***Cannabis sativa* L. seeds of various cultivars, will be imported from companies listed in our attached SOURCE MATERIAL commitment letters, and MUST be under permit from the US Drug Enforcement Administration. These companies are already demonstrating compliance with their own federal regulations and are successfully supplying researchers around the world.**

Quantities to produce an initial final product volume of 125 to 150 pounds per month will be acquired. Approximately 300 seeds for genetic material will initially be acquired. Due to the nature of horticulture production, it is standard practice to maintain mother plants that will be cloned, negating the need for regular, outside purchasing of genetic material for ongoing operations.

Other materials purchased on a regular basis and used to manufacture cannabis, include liquid nutrients and soil, purchased in quantities commensurate with production levels.

4. Please provide the name, address, method of shipment and method of delivery for each supplier from which your firm intends to procure materials for the manufacture of the controlled substance(s).

Method of shipment: same as NIDA/UNIVERSITY OF MISSISSIPPI which is FEDEX

5. Does your company have a firm commitment from each supplier of raw material? What is the time period of this agreement and what quantity of raw material will each supplier be able to supply? Please attach copies of commitment letters from each supplier

PLEASE SEE ATTACHMENTS:
SOURCE MATERIAL: PERFECT PLANTS SIGNED LETTER – PAGE 28
SOURCE MATERIAL: BETTER MEDICAL GRADE CANNABIS – PAGE 29
SOURCE MATERIAL: TRUE HEALTH COMPANY – PAGE 30

THE INFORMATION IN THIS DOCUMENT IS CERTIFIED AS ACCURATE AND CURRENT AS OF:

(SIGNATUR]  (DATE):_____ **12-17-2016**___

3

U.S. DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
BULK MANUFACTURER QUESTIONS
SCHEDULE I & II CONTROLLED SUBSTANCES

Company Name: **Scottsdale Research Institute SRI**
SOURCE MATERIAL: xMed21 - PAGE 31

We are in regular communications with these suppliers and we have commitment letters attached. Each of these companies has agreed to supply us genetics for the next 2 years after licensing confirmed and only if their DEA 357 form permits are approved.

6. **What quantity of each controlled substance does your company anticipate producing in bulk?**

During the first 6-9 months, we initially plan to cultivate over 100 lbs. per month for our own Phase 3 trials with the FDA. During the second year of operation we will ramp up production to over 2,000 lbs. per month, meeting the market demand for multiple different phenotypes.

7. **Who are your current and prospective customers (name, address and DEA) for <u>each</u> controlled substance?**

As we are not currently licensed, we do not have a customer base. Once we are licensed, we will be supplying our internal, FDA sanctioned and licensed, clinical trials. We will supply Academic and private researchers across the country with highly refined, consistent cannabis phenotypes. We intend to develop a sophisticated breeding program that will ensure the growth of truly unique genotypes, providing researchers with a consistent supply of medical product, unlike that which is currently available through the University of Mississippi cultivation program.

Scottsdale Research Institute (SRI)

Scottsdale Research Institute, LLC
1225 West Deer Valley Road, Phoenix, AZ 85027 USA
Phone: +1 (623) 587-5660

DEA REGISTRATION NUMBER:
schedule 1: RS0496225
schedule 2–5: BS5887255

a. **What product(s) (e.g., active pharmaceutical ingredient or API, dosage units, materials for clinical research) does your company intend to sell to each customer listed?**

Our genetic breeding program will expand on the already existing THC/CBD Phenotypes currently available through NIDA. SRI plans to strive to cultivate new cannabinoid phenotypes available to

THE INFORMATION IN THIS DOCUMENT IS CERTIFIED AS ACCURATE
AND CURRENT AS OF:

(SIGNATURE)  (DATE):_____ **12-17-2016**___

U.S. DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
BULK MANUFACTURER QUESTIONS
SCHEDULE I & II CONTROLLED SUBSTANCES

Company Name: **Scottsdale Research Institute SRI**

scientists that may also be of pharmacological interest. For instance, there is extensive curiosity about the cannabinoids THC V and CBG and other cannabinoids that are not readily available through NIDA currently.

US researchers are now demanding diverse phenotypes to treat conditions ranging from neuropathic pain to epilepsy (Bostwick, 2012). The functions of enzymes involved in cannabinoid biosynthesis that apparently evolved by gene duplication are therefore obvious candidates for selective breeding efforts and other kinds of genetic engineering, which we intend to fully explore through our breeding program.

b. What quantity of each substance have your customers indicated they would purchase?

The exact quantity to be purchased can only be approximated at this point in time. At a minimum we know that the annual quota for cannabis at the University of Mississippi program is 1,400 lbs. We also know that our own demand is approximately 1,200 lbs./ annually. We expect the process of achieving GMP grade cannabis for research could take us over full year to achieve. . Hence, we can only predict what researchers needs will be in 1 to 2 years. We will produce the highest quality standardized cannabis and researchers will view SRI phenotypes as a viable complement to the excellent efforts of the current supplier at U of Mississippi. Having a second supply of research grade cannabis is crucial and we can fill the void of phenotypes that are currently not in NIDA development.

However, we do know that in approximately two years we will be applying for over 100 kg of specific phenotypes of cannabis to commence phase 3 trials with the FDA. So we know that our first customer will likely be SRI. We will be striving to move into phase 3 FDA controlled trials by 2019.

c. For what purpose are your customer(s) purchasing the controlled substances? (e.g., dosage form development, clinical trials, FDA approval). Please be specific as it relates to each customer and each controlled substance identified above.

Scottsdale Research Institute SRI is preparing for phase 3 FDA approved drug development clinical trials with cannabis. Our ultimate goal involves evaluating whether cannabis can be turned into a prescription medicine. The only way to conduct this analysis is through phase 3 trials. However the current supply of research cannabis from cannot be utilized for prescription drug development. It can only be used for academic research. Which is why we are seeking to cultivate a new supply of cannabis to be used for these Phase 3 FDA trials.

THE INFORMATION IN THIS DOCUMENT IS CERTIFIED AS ACCURATE AND CURRENT AS OF:

(SIGNATURE)  (DATE):_____ **12-17-2016**___

U.S. DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
BULK MANUFACTURER QUESTIONS
SCHEDULE I & II CONTROLLED SUBSTANCES

Company Name: **Scottsdale Research Institute SRI**

8. **What are your company's future plans with regard to the manufacture of controlled substance(s)? Please provide detailed information, as possible, including timelines, and plans to expand your production facility, addition of equipment, product development activities, research and development, batch names and batch sizes and any FDA approvals.**

Scottsdale Research Institute SRI is currently conducting an FDA approved Phase 2 randomized controlled trial evaluating Safety/Efficacy of Cannabis for military veterans with PTSD. We plan to move into Phase 3 trials in next 3 years and will need a supply of cannabis other than NIDA, which is allowed to be used for drug development research.

Upon receiving our DEA Schedule 1 license for Bulk Manufacturing, and we are cleared to move forward with production, we will first finalize the build out of the facility. This should take approx. 6 months. Build out will include a tissue culture lab as well as space for a breeding program. Aside from all the standard equipment for precision agriculture (fertigation control, reverse osmosis water treatment, monitoring system, etc.), other equipment purchases include:
We will purchase Rotovape to eventually enable solvent less cannabis extractions into tincture/oil/concentrates (depending on requests from US researchers).
Batch names/Batch sizes are impossible to predict until researchers learn that we are available to provide study drug for them, and will then send us requests for certain phenotypes in certain amounts.

9. **When does your company anticipate commencing sales or other distribution of each controlled substance?**

Scottsdale Research Institute SRI will not commence any sales/distribution until we have proof of GMP grade manufacturing of standardized cannabis for research. Once we can prove we have research grade cannabis, and the FDA provides us their stamp of approval of GMP grade quality, then we will work with the DEA to make sure we have all of the proper permissions and drug accountability logs in place to commence. But nothing will start without all of the proper approvals in hand.

10. **Do you currently have any other controlled substance registrations from the DEA? If so, please include the name, DEA number(s), business activity, drug schedules and expiration dates(s).**

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U.S. DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
BULK MANUFACTURER QUESTIONS
SCHEDULE I & II CONTROLLED SUBSTANCES

Company Name: **Scottsdale Research Institute SRI**
Please see attached copies of licenses – pages 34 & 35
DEA REGISTRATION NUMBER:
schedule 1: RS0496225
schedule 2–5: BS5887255
EXPIRES: 2-28-2017 (application for extension submitted)

For description of business activity, please see attached:
SCOTTSDALE RESEARCH INSTITUTE MISSION STATEMENT – Page 19
SCOTTSDALE RESEARCH INSTITUTE VISION AND OBJECTIVES STATEMENT – Pages 20-27

11. **Please describe your company's past experience in manufacturing controlled substances. Please be specific with regards to dates, types of manufacturing activity, and names and schedules of controlled substances manufactured.**

Scottsdale Research Institute SRI has no experience manufacturing Controlled Substances, but has experience managing the Schedule 1 drug we've purchased from NIDA earlier this year. We know how to maintain proper drug accountability, prevent diversion and have demonstrated impeccable compliance to date.

SRI has a robust plan in place to hire an experienced team of grow operators. SRI has been involved with the burgeoning cannabis sector for over five years and has deep connections within the sector from which to mine talent.

12. **Have you or anyone else who will be involved in the ownership or operation of your company previously manufactured or distributed any controlled substance without a DEA registration authorizing such activity? For each such person, please separately indicate dates, types of manufacturing or distribution activity, names of controlled substances, and quantities manufactured or distributed. Do not include persons who own less than 5 percent of the company.**

NONE

13. **Has primary ownership of your company if your company changed of the past 12 months? If so, please provide details.**

Scottsdale Research Institute SRI has maintained same ownership for past 2 years since initial inception.

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U.S. DEPARTMENT OF JUSTICE
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BULK MANUFACTURER QUESTIONS
SCHEDULE I & II CONTROLLED SUBSTANCES

Company Name: **Scottsdale Research Institute SRI**

14. **If your company is applying to obtain a registration as a bulk manufacturer because your company is unable to purchase the needed controlled substance(s) from existing bulk manufacturers, please provide the names of the existing registered bulk manufacturers you contacted. Please include dates of contact, person contacted, and method of contact.**

In correspondence directly from NIDA Program Director, Hari Singh, he states that NIDA "has very limited supply"…
Please see attached documentation (email correspondence):
Dr. Hari Singh Evidence of Limited Supply of Cannabis via U Miss/NIDA Program – PAGE 33

Hari H. Singh, Ph.D.
Program Director
Drug Supply & Analytical Services
Chemistry & Physiological Systems Research Branch
Division of Basic Neuroscience & Behavior Research
National Institute on Drug Abuse
National Institutes of Health
6001 Executive Boulevard, Room # 4282, MSC 9555
Bethesda, MD 20892-9555
Phone: (301) 435-1310
Fax: (301) 594-6943
e-mail: hsingh1@nida.nih.gov

15. **Please describe in detail whether your company's proposal to bulk manufacture controlled substances will promote technical advances in the art of manufacturing these substances and in the development of new substances.**

The goal would be to develop one of the best breeding programs in the country that can serve scientists nationally and give them access to some of the most desirable chemo types in the US. These are chemo types that are not currently available NIDA drug supply. Scottsdale Research Institute SRI intends to implement all of the state of the art precision agriculture techniques including an on-site cannabis tissue culture laboratory, the latest technology for Genotyping, quantitative trait locus (QTL) mapping, and gene expression assays associated genomic regions and loci with phenotypes to demonstrate that despite the linkage of separate loci for THCA synthase and CBDA synthase, it is variation at the CBDA synthase locus alone that accounts for the main difference between the cannabinoid profiles of marijuana.

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SCHEDULE I & II CONTROLLED SUBSTANCES

Company Name: **Scottsdale Research Institute SRI**

Note: In answering question 16 and 17, please note that, your company bears the burden of demonstrating that either the existing supply or competition is inadequate within the meaning of 21 USC § 823 (a)(1). Particular consideration should be given to whether the existing registered bulk manufacturers of the controlled substance for which you seek registration can produce an adequate and uninterrupted supply of this substance under adequately competitive conditions. In assessing adequacy of supply, DEA generally focuses on the ability of existing registered bulk manufacturers to provide the *quantity* of material needed to supply the lawful needs of the United States. In assessing the competition, DEA has traditionally focused on the historical and present prices charged to those who lawfully acquire the controlled substance from the existing registered bulk manufacturers, and whether such prices are reasonable.

16. **Adequacy of supply – Are you seeking to become registered based on the contention that the existing registered bulk manufacturers of the controlled substance are incapable of producing an adequate and uninterrupted supply of that substance to meet lawful needs of the United States? If so please explain in detail.**

Scottsdale Research Institute SRI contends that the current supply of cannabis being provided does not meet the necessary standards currently demanded by researchers, specifically drug manufacturers. Although the current supply is adequate for academic study, variety of cultivars and consistency of chemical profile are not available.

PLEASE SEE ATTCHED EMAIL CORRESPONDENCE FROM DR. HARI SINGH: UMISS / NIDA PRGRAM – PAGE 33

17. **Adequacy of competition – Are you seeking to become registered based on the contention that the existing registered bulk manufacturers of the controlled substance are incapable of supplying the lawful need of the United States under adequately competitive conditions? Is so please answer the following questions:**

a. **Regarding your competitors, products, and prices, please explain why those suppliers are inadequate?**

Scottsdale Research Institute SRI contends that NIDA Cannabis cannot be used for FDA Phase 3 trials. This is the biggest limitation of NIDA study drug. NIDA produced Cannabis can only be used for academic research but not for drug development.

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U.S. DEPARTMENT OF JUSTICE
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BULK MANUFACTURER QUESTIONS
SCHEDULE I & II CONTROLLED SUBSTANCES

Company Name: **Scottsdale Research Institute SRI**

b. Why are current prices charged by your competitors unreasonable?

Current NIDA pricing is NOT unreasonable.

a. Please provide evidence showing that current market prices are clearly and persistently excessive.

Current NIDA pricing is NOT excessive. Current market prices for NIDA study drug are reasonable. SRI just purchased 4 Kg of Cannabis from NIDA and felt pricing was fine. Many of my research colleagues have told me NIDA provides cannabis for NIDA studies at no cost to the scientists which is even more reasonable.

b. Please state your prices and explain why they are more competitive than the current prices in the existing market.

Scottsdale Research Institute SRI can only approximate pricing at this time. Pricing will mirror national price averages. Currently, high grade cannabis sells between $15-25 / gram.

c. Provide evidence that you can produce the controlled substance (s) in question at a lower cost than your competitors.

There are currently no suppliers of appropriate cannabis for Phase 3 clinical trials. We are confident we can keep prices low by utilizing standardized growing methodologies and state of the art efficiency systems designed to save electricity and reduce environmental waste.

Note: To assist you in answering question 18, applicants are advised to consult the DEA Policy Statement titled " Application to Become Registered Under the Controlled Substances Act To Manufacture Marihuana to Supply Researchers in the United States," which was published in the Federal Register on August 12, 2016 (81 Fed. Reg. 53846).

18. **Bulk Manufacturer Marihuana Growers Only**

a. Is this registration for an indoor or outdoor marijuana grow or both?

Scottsdale Research Institute SRI intends to eventually grow both indoors and through a greenhouse system. But for the first 2 years, we will focus on indoor only to ensure we have true

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SCHEDULE I & II CONTROLLED SUBSTANCES

Company Name: **Scottsdale Research Institute SRI**
precision agriculture with the capacity to grow cannabis to exact GMP specifications in standardized fashion.

b. Provide the exact location of the plot(s) of land on which the marihuana will be grown and provide a detailed description of the land or indoor grow location. Include the size of plot or grown room, estimated number of plants and theoretical and estimated yield from those plants.

PLEASE ATTACHMENTS:
15550 NORTH 78TH STREET FLOOR PLAN #1 – PAGE 39
15550 NORTH 78TH STREET FLOOR PLAN #2 – PAGE 40
15550 NORTH 78TH STREET FLOOR PLAN #3 – PAGE 41
15550 NORTH 78TH STREET PICS #4 – PAGE 42
15550 NORTH 78TH STREET PROPERTY #5 – PAGE 43

Scottsdale Research Institute SRI has secured the opportunity to purchase a 34,000 sq. ft. building in Scottsdale, AZ. We have been working internally and with industry experts on the optimum space utilization for providing yields on a weekly or monthly rotation.

Based upon our current design parameters this facility could be utilized as follows:

Flowering Space - 11,700 sq. ft.
Vegetation Areas - 3,900 sq. ft.
Mother/Clone Area - 1,300 sq. ft.
Trim/Nutrient Mix Areas - 650 sq. ft.
Cure Area - 650 sq. ft.
Lockers/showers - 650 sq. ft.
Shipping/Receiving - 650 sq. ft.
Safe Storage - 500 sq. ft.

With this amount of space SRI would utilize right at 20,000 sq. ft.

We are confident this setup could yield approximately 450 - 500 lbs./month of flower in case DEA quotas increased suddenly.

This will be an indoor grow initially, but we hope to expand to a greenhouse system (for reduced environmental impact) in the future once we can prove GMP grade Cannabis in our indoor facility.

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c. **Who owns the land or property (if indoor grow)? Is the land or property leased? If yes, who is the leasee?**

Scottsdale Research Institute SRI will own the property. We are in active purchase discussion with current owner and property has been on the market empty for 6 months so seller is eager to negotiate. We will offer a deposit sufficient to ask the owner to hold until we've secured a DEA license, however long that takes. That is our commitment to ultimately purchase the bldg. We intend to invest the capital to guarantee this facility will be secure for the long-term.

d. **Have you read the August 12, 2016, DEA Policy Statement titled "Application to Become Registered Under the Controlled Substances Act To Manufacture Marihuana to Supply Researchers in the United States," which was published in the Federal Register on August 12, 2016 (81 Fed. Reg. 53846)?**

Yes we have read this policy statement and agree to abide by all of its tenets.

e. **Are you proposing to engage in any manufacturing activities involving marihuana beyond growth/cultivation? (This would include any processing, extraction, packing, labeling or other activities that fall within the definition of "manufacturer in 21 U.S.C. §802(15). If so, please indicate that locations(s) where such additional manufacturing will take place and, for each location, provide the information specified in question c.**

Scottsdale Research Institute SRI is committed to housing all steps of manufacturing within the same building. Processing/extraction and packaging/labeling will occur under one secure roof. We intend to perform internal lab testing to ensure our plants are replicating the genetic profile that were originally certified. But more importantly, we want to assure we have plants that meet highest standards for patient safety. There will be equipment on-site including LC/GCMS machines for testing cannabinoids, terpene profiles, and mold/microbial testing.

Mold/microbes presence and terpene profiles is information that is not currently provided by NIDA to it's customers. By conducting these tests and sharing this crucial information with our customers, this will also provide a much needed service that is not available and distinguishes us from other bulk manufacturers.

PLEASE SEE ATTACHMENTS:
DEA SCHEDULE I ANALYTICAL LAB LICENSE CONSULTANT LETTER – PAGE 36
DEA SCHEDULE I ANALYTICAL LAB COST PROJECTIONS – PAGE 37
DEA SCHEDULE I ANALYTICAL LAB EQUIPMENT LIST – PAGE 38

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Company Name: **Scottsdale Research Institute SRI**

f. Are you a contract manufacturer? If yes, who is your sponsor?

Scottsdale Research Institute SRI is NOT a contract manufacturer. Dr. Sisley has a Schedule 1 license only as a researcher currently.

g. Identify all persons who will be responsible for deciding, on behalf of you or your company, how much marijuana you will seek to grow and the persons to whom you plan to distribute the cannabis materials you produce. For each such person, please provide the full name, address, and means by which such person may be contacted (e.g., telephone number or email).

Scottsdale Research Institute SRI is currently owned by Dr. Sue Sisley MD and Dr. Hanna Sisley MD and these 2 physicians will be responsible for deciding the amount of cannabis to grow annually and who will be legally eligible to purchase the study drug.

Sue Sisley MD
12622 N. 81st ST
Scottsdale, AZ 85260
(480) 326-6023
suesisley@aol.com

John Pickering PhD
275 Blue Heron Drive
Athens, GA 30605
pick@discoverlife.org

Hanna Sisley MD
12634 N. 81st ST
Scottsdale, AZ 85260
hannasisleymd@aol.com

h. If you are seeking to grow marijuana in order to supply cannabis materials to other manufacturers or researchers, do you understand and agree that you will only be permitted to distribute such material to persons who have obtained a DEA registration authorizing them to conduct such activities?

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Company Name: **Scottsdale Research Institute SRI**

Yes, absolutely. We will ONLY distribute to other researchers who can confirm they have proper/up-to-date DEA registration and have completed the necessary forms (and obtained the final approvals) to enable such distribution.

i. Are you seeking this registration exclusively for the purpose of supplying researchers as part of a contract with the National Institute on Drug Abuse? If so, please indicate the status of such contract.

Scottsdale Research Institute SRI is NOT emergently striving for a contract with NIDA, but we would be delighted to explore that in the future. SRI would be willing to supply NIDA researchers with study drug. We hope to have the unique varieties of Cannabis that NIDA researchers may desire. But we have not yet begun a dialogue with NIDA until we actually have a Schedule 1 Bulk Manufacturer license approved.

j. If you are seeking this registration to manufacture marijuana for a purpose other than fulfilling a contract with the National Institute on Drug Abuse, do you understand that, for the reason set forth in DEA's August 12, 2016, policy statement, DEA will request as a condition of you becoming registered, that you enter into a memorandum of agreement under which you will be required to obtain written approval from DEA before each distribution of marijuana to other entities?

Scottsdale Research Institute SRI understands the August 12, 2016 policy statement and agrees to fully abide by this MOA. We are already accustomed to obtaining written approvals for all moves made under Dr. Sisley's current Schedule 1 researcher license. We've already demonstrated good compliance with this mandate.

k. In what form and quantities will you distribute your material? Specifically, for each marihuana product (e.g., plant, resin) for each customer (name, address, and DEA number). Please provide the quantities to be distributed.

Scottsdale Research Institute SRI will initially be distributing dried flower product in quantities appropriate for research. SRI is unable to name customers nor exact quantities at this time. It's too early to estimate this information. A robust industry currently exists, consisting of multiple pharmaceutical start-up companies that would demand our unique product.

l. What are the theoretical cannabis alkaloid content (e.g., THC, CBD, etc) of those materials in (k)?

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Company Name: **Scottsdale Research Institute SRI**

Scottsdale Research Institute SRI aims to produce a wide array of phenotypes, expressing a full spectrum of alkaloid contents. From low or no THC to THC potency that exceeds the current NIDA limits of 12%THC. SRI will also provide access to higher quantities of unique cannabinoids such as THCV and CBG, and variants with broad terpene profiles, etc.

m. Do you plan to import seeds or other controlled substance starting material? If yes please indicate from what country, the name address, contact information of such supplier and whether the supplier is registered with DEA to import controlled such material.

Scottsdale Research Institute SRI hopes to import starting materials from at least 2 different countries:
Amsterdam, Canada, Czech Republic and possibly Israel (if we are unable to secure DEA permits with one of the 1st two) The seeds will probably be imported from one of these companies highlighted in attached letters, who will need to gain proper permits and approvals and must have a track record of good compliance in managing their existing federal license within their own country.

(It should be noted that SRI has been unable to identify a single legal source of Cannabis for research within the US. We asked Dr. El Sohly at University of Mississippi and he refused to sell genetics to any future Schedule 1 growers claiming their genetics are IP owned by U MISS).

In addition, we are in communication with these 4 companies above (see attached SOURCE MATERIAL letters) that both have expressed a commitment to obtain the proper governmental license for export and to assist SRI in preparing the DEA FORM 357 to import genetics for research. Again, no importation of seeds will be planned until all the proper approvals are in place.

Mailing Address

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Company Name: **Scottsdale Research Institute SRI**
Drug Enforcement Administration
Attn: 303 Processing/Marquita Brown/DRGR
8701 Morrissette Drive
Springfield, VA 22152

Facsimile:

Fax# (202) 307-8101
Attn: 303 Processing/Marquita Brown/DRGR

If you have any questions, please contact one of the following individuals:

Name	**Telephone#**
Angela Francis, Unit Chief **AFranscis@usdoj.gov**	**(202) 598-2600**
Marquita Brown, Program Analyst **Marquita.L.Brown@usdoj.gov**	**(202) 353-1199**
Scott Doubet, Staff Coordinator **Earl. S. Doubet@usdoj.gov**	**(202) 598-8419**
Inez Davis, Staff Coordinator **Inez. M.Davis@usdoj.gov**	**(202) 598-8379**
Irvin Reaves, Staff Coordinator **Irvin.X.Reaves@usdoj.gov**	**(202) 598-8736**

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Company Name: **Scottsdale Research Institute SRI**

Sandra White-Hope, Staff Coordinator **(202) 598-2893**
SKWhite-Hope@usdoj.gov

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Scottsdale Research Institute, LLC
1225 West Deer Valley Road, Phoenix, AZ 85027 USA
Phone: +1 (623) 587-5660

SRI MISSION:

The purpose of the Scottsdale Research Institute, LLC, an Arizona-based Limited Liability Company is to coordinate rigorous, scientific studies to assess the safety and efficacy of cannabis and cannabis compounds for treating medical conditions.

The SRI Institute will coordinate and support cannabis research throughout the State of Arizona and beyond. Research will focus on the potential medicinal benefits of cannabis for diseases and conditions as specified by the National Academy of Sciences, Institute of Medicine Report (2017 & 1999) and by the Workshop on the Medical Utility of Marijuana, National Institutes of Health (1997).

The SRI will b strive to conduct high quality, controlled scientific studies intended to ascertain the general medical safety and efficacy of cannabis and cannabis products and examine various forms of cannabis administration. The Institute will be seen as a model resource for health policy planning by virtue of its close collaboration with federal, state, and academic entities. The SRI will also highlight the current barriers to federally-regulated Marijuana Research.

The following diseases and conditions will constitute areas of emphasis for research funding:

* Post-Traumatic Stress Disorder among Combat Veterans and First-Responders
* Substitution therapy for opioid dependence, benzodiazepine withdrawal etc.
* Agitation in Alzheimer's disease
* Severe appetite suppression, weight loss, and cachexia due to HIV infection and other medical conditions
* Chronic pain, particularly neuropathic pain
* Severe nausea and vomiting associated with cancer and its treatment
* Severe muscle spasticity caused by diseases such as multiple sclerosis
* Autism, Autism Spectrum Disorders and other pervasive developmental disorders.

The Institute will call for a 10-year program overseeing objective, high quality medical research that will “enhance understanding of the efficacy and adverse effects of marijuana as a pharmacological agent,” stressing that the project “should not be construed as encouraging or sanctioning the social or recreational use of marijuana”.

The Institute will also develop an awareness campaign addressing the past blockades to federally regulated whole plant marijuana efficacy research while simultaneously applauding the DEA for their announcement to end the NIDA monopoly.

The SRI will address new barriers to conducting FDA-approved Marijuana Drug Development Research, and continue to build relationships with federal agencies including DEA, FDA, NIDA, and elected officials & other community leaders who care about these hurdles.

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1225 West Deer Valley Road, Phoenix, AZ 85027 USA
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The Scottsdale Research Institute takes advantage of its unique understanding of metabolic processes to provide innovative treatment options for unmet patients' medical needs. Cannabis use has an extensive history dating back thousands of years, and currently there are thousands of peer-reviewed scientific publications that document the underlying biochemical pathways that cannabinoids modulate.

At The Scottsdale Research Institute, we use an inquiring approach to discover and develop novel whole plant & cannabinoid-based therapies to improve patients' lives.
Our founders are committed to fostering and maintaining a bold, pioneering spirit fostering the true nature of innovation from which cutting edge ideas flourish and translate into evidence-based solutions.

We are dedicated to working closely with local, national and international regulatory agencies to provide access to high quality, first class cannabinoid pharmaceuticals to those patients critically in need of new treatments for life threatening and debilitating conditions.

The Scottsdale Research Institute's clinical trial material will come from the cultivation and production facilities that are cGMP compliant, surpassing high quality standard industrial and food processing requirements.
The Scottsdale Research Institute has recently completed and submitted DEA form 225 to request a DEA schedule one license for a federally legal cultivation site to grow for academic/private cannabis research.

The Scottsdale Research Institute works with leading experts in drug development, medicinal characterization, and clinical research to develop, produce, and commercialize novel therapeutic approaches for the treatment of multiple critical ailments from cancer and infections to age-related illnesses and neurobehavioral disorders.
Our products will be rigorously evaluated through intensive clinical trials examining both safety and efficacy.
The Scottsdale Research Institute will work to put both whole plant and medical cannabinoid formulations developed from one or more of the cannabinoid compounds found in the cannabis plant through the entire FDA drug development process.

SCOTTSDALE RESEARCH INSTITUTE

Scottsdale Research Institute, LLC
1225 West Deer Valley Road, Phoenix, AZ 85027 USA
Phone: +1 (623) 587-5660

Our long term focus is to treat one of the most important diseases in the world, cancer.
In 2017, The Scottsdale Research Institute will submit a patent application in US & Europe entitled "High THC cannabis oil for squamous cell carcinoma" (BFF-SCC-1). The subject of the patent is development of cannabinoid-based formulations to treat specific skin cancers.

BASIS & PHILOSOPHY
Cannabis plants have extensive history of medical and agricultural use dating back thousands of years.
To date hundreds of natural constituents covering several chemical classes have been isolated and identified from the Cannabis plant.

SOME KEY PHYTOCANNABINOIDS ARE:
* tetrahydrocannabinol (THC)
* cannabidiol (CBD)
* cannabigerol (CBG)
* cannabichromene (CBC)
* cannabinol (CBN)

These cannabinoids belong to the chemical class of terpenophenolics, of which 135 have been uniquely identified in cannabis, including the most psychoactive cannabinoid, THC. Some applications of cannabinoids have been well established in peer-reviewed literature such as for alleviating nausea and stimulating the appetite for people with AIDS and cancer. Other well-known uses include easing chronic pain and reducing muscle spasms associated with multiple sclerosis and spinal cord injuries.
The pharmacology of THC has been widely studied, while many other identified cannabinoids are still poorly characterized pharmacologically and biologically, with new activities for cannabinoids consistently being discovered.

The Scottsdale Research Institute is developing novel cannabis based approaches to treat the world's most deadly illnesses. We learn from patients/families about the healing properties of cannabis medicines. Our immediate focus is the development of cutting edge treatments for autism, opioid epidemic/pain, PTSD/Suicide, and cancer.

The Scottsdale Research Institute's future endeavors include neurobehavioral

SCOTTSDALE RESEARCH INSTITUTE

Scottsdale Research Institute, LLC
1225 West Deer Valley Road, Phoenix, AZ 85027 USA
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disorders including autism, attention deficit disorder, post-traumatic stress disorder; and an application of the anti-inflammatory activities of cannabis in the management of age-related illnesses.

The endocannabinoid system possessed by all vertebrates regulates all body systems and maintains homeostasis. As such, the mechanisms of phytocannabinoids' biological impact are multidimensional.
While concentrating on our core activities of discovering and developing treatments that will make a meaningful difference in patients' lives, we remain mindful that we have other responsibilities to the clinicians who utilize our drugs, health authorities around the world, our shareholders, our employees, and the communities in which we

live and work. We continually strive to improve our corporate responsibility standards and activities, implementing comprehensive ethical standards and undertaking patient and community progressive initiatives.
These principles reflect the mission of The Scottsdale Research Institute to provide innovative therapeutics for unmet patient medical needs.

We feel that the correct way is to look at the industry from a bio-pharmaceutical standpoint, in a manner that allows whole plant & cannabinoid-based products to modulate the endocannabinoid system to treat multiple conditions.
Scientifically, The Scottsdale Research Institute knows this is the beginning of one of the greatest expansions of medicine and industry we will ever experience in our lifetime.

Partnerships

Our clinical trials will concentrate on the role of medicinal cannabinoids across a range of conditions, and will require coordination of the many regulatory, medico-legal, ethical and logistical issues in conducting such research. Our researchers intend to collaborate with key experts and clinicians in the nominated priority areas.

The initiative will also include a core chemistry component to allow analysis of existing preparations (tinctures, oils, plant materials etc.) of medicinal cannabis being used in the community, and the future legal preparation of novel formulations to be used in clinical studies. A medicinal chemistry component will drive the creation of new medications based on our emerging mechanistic understanding of the how cannabinoids treat disease states.

Recruitment

To undertake Phase I, II and III human trials in our revered US Military Veteran community, and other clinical and laboratory-based studies with Veteran volunteers to provide definitive

SCOTTSDALE RESEARCH INSTITUTE

Scottsdale Research Institute, LLC
1225 West Deer Valley Road, Phoenix, AZ 85027 USA
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evidence of the safety and efficacy of cannabinoid-based medicines for a range of diseases. SRI will collaborate with diverse Veterans Service Organizations to spread accurate information about study findings, newly enrolling clinical trials seeking volunteers and striving to serve as a resource to the Military Veterans community for accurate and up-to-date explanations about current state of Cannabis research.

RESEARCH PROJECTS

The SRI will strive to conduct high quality, controlled scientific studies intended to ascertain the general medical safety and efficacy of cannabis and cannabis products and examine various forms of cannabis administration.

The Institute will be seen as a model resource for health policy planning by virtue of its close collaboration with federal, state, and academic entities. The SRI will also highlight the current barriers to federally-regulated Marijuana Research.

TARGETS

The initial aims of the SRI will be to assess and develop whole plant and cannabinoid-based treatments for the following conditions:

Autism Spectrum Disorder (ASD) – One of our primary objectives in the first wave of research will be to shed light on the efficacy of whole plant cannabis for Autism and ASD. Given the known role of the endocannabinoid system in Autism Spectrum Disorder it seems entirely possible, if not likely, that cannabinoid rich botanical extracts from cannabis can be utilized as useful agents targeting the pathophysiology of ASD, as well as the many debilitating symptoms and conditions associated with it. The wealth of options that cannabis has to offer those that suffer from ASD is not currently legally permitted, (except soon through certification by Pennsylvania Medical Cannabis Program).
But what about the known negative effects associated with THC?
Acute and chronic administration of THC has been demonstrated to cause mild cognitive deficits related to memory and learning via CB1 activation in healthy brains (Sarne 2011). While this characteristic is not to be downplayed or overlooked, it should be pointed out that low doses of THC also activate preconditioning and post-conditioning mechanisms that protect the brain from more severe insults (Sarne 2011). Which has more potential for damage, THC or the slew of other environmental toxicity, oxidative stress, and neuronal insult factors that autistic brains are suggested to be more vulnerable to (Kern 2006)? That answer seems dependent on the severity of the condition, and it's important to note that we're only referring to truly debilitating forms of ASD. Equally relevant is that the cognitive deficits are inhibited by CB1 antagonists like CBD (Sarne 2011).

TBI Traumatic Brain Injury/CTE Chronic traumatic encephalopathy - A major priority over the first three years will be obtaining a mechanistic understanding of how cannabidiol (CBD) works to treat TBI/CTE, and to screen other cannabinoids to

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identify others with similar or even greater therapeutic potential for this indication.

Recent evidence indicates that CBD and the related compound CBDV have efficacy in the treatment of TBI/CTE. However, at a neuronal and cellular level it is not known how CBD has such dramatic therapeutic effects, and whether other plant-based cannabinoids may have greater therapeutic effects and/or potency.

In the first three years our aim is to obtain a mechanistic understanding of how CBD works in TBI/CTE and identify which of the big 10 cannabinoids have similar or improved therapeutic potential. We will also contribute our expertise to the current Boston university CTE Center examining cannabinoids in TBI/CTE.

Cancer - Research to date shows that cannabinoids can alleviate the nausea and wasting seen in cancer and HIV patients. Preliminary results in cancer cells also suggest they have the potential to inhibit various tumours and overcome resistance to standard chemotherapeutic agents.

The SRI will allow us to screen the efficacy of multiple cannabinoids in certain types of cancer. Our initial focus will be on glioma (brain cancer) and squamous cell cancer (a type of SKIN cancer) – both of which have poor prognoses due to a lack of satisfactory treatment options. Research will initially involve testing cannabinoids in cellular and animal models of these cancers, leading to clinical trials with the most promising candidates.

Chronic pain - Many patients suffering from chronic pain and inflammatory disease states use illicitly sourced cannabis to ease their suffering. However the most effective cannabinoids to use for pain and inflammation are not yet known. Chronic pain conditions comprise three of the top ten clinical problems contributing to burden of disease in US (back pain no.1, neck pain no.4, and migraine no.8), reducing quality of life and costing the taxpayer many millions of dollars each year in health care costs and lost productivity. The SRI will bring together medical and scientific experts and consumer representatives to undertake innovative world-leading preclinical and clinical research plan in this key area.

Obesity and cachexia/wasting syndrome - Obesity and diabetes are major diseases of the modern age and are the subject of intensive research efforts. Our researchers will explore the potential of cannabinoids to treat metabolic disorders via their effects on the brain and the bodily systems that regulate appetite and fat metabolism.

Importantly while it is known that some cannabinoids (e.g. THC) stimulate appetite, we believe that others will have the opposite effect, leading to weight loss and elevated metabolism of body fat stores. The appetite stimulating effects of some cannabinoids may be of use in chemotherapy-induced wasting syndrome and the other disorders that make it difficult to maintain weight-nourishment.

Addictions and mental health - We also see great potential for clinical trials of whole

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plant cannabis and individual cannabinoids in the area of addictions and for mental health disorders such as schizophrenia and PTSD.

We will leverage the investment in the SRI to extend our ongoing work exploring Cannabis as Replacement Therapy for Opioid Dependence, providing safer and more effective treatment options for those who are trying to quit opioids (heroin & pain pill) abuse.

US has one of the highest rates of methamphetamine abuse in the world, leading to major health problems for users and their families including psychosis, aggression and criminality. One of our goals of the Initiative would be to probe the ability of cannabinoids to reduce cravings for drugs such as methamphetamine and cocaine. There is encouraging preliminary evidence that CBD may have powerful anti-craving and antipsychotic effects.

Preclinical and early human research into the ability of cannabinoids to ameliorate anxiety and psychosis-like states seen in post-traumatic stress disorder (PTSD) and Schizophrenia is already underway and would be significantly accelerated with support from the SRI.

Dementia - The world's population is aging and many individuals are faced with an increased risk of developing dementia. Dementia affects around 35 million people worldwide and there are limited treatment options. There is emerging literature showing that cannabidiol has the potential to enhance memory by limiting brain pathology observed in animal models of Alzheimer's disease, and this research area could be considerably accelerated and expanded by the SRI.

Surveying current medicinal cannabis use - It is critical to gather as much information as possible on the medicinal use of cannabis in order to further our understanding and evidence base. We will therefore conduct a large national survey of existing users of medicinal cannabis products and their perceived effectiveness among users. Assuming official regulatory approval, we will also provide chemical analysis of the products currently being used so as to link a cannabinoid profile to perceived effectiveness and also to check for contaminants (e.g. heavy metals, pesticides, molds) in currently used products. This early study will provide important evidence concerning the optimal composition of cannabinoids for treating various disease states.

SRI TEAM

The team will consist of 8 people as follows (detailed resumes are attached):

- Dr. Sue Sisley, MD - Scottsdale Research Institute
- Dr. John Pickering, PhD – University of Georgia

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Phone: +1 (623) 587-5660

- Dr. Lumir Hanus, PhD - Hadassah University, Israel
- Dr. Amy Emerson, PhD - MAPS
- Dr. Paula Riggs, MD - University of Colorado DENVER, Anschutz Medical campus
- Dr. Laura Borgelt PharmD - University of Colorado DENVER, Anschutz Medical campus
- Christina Lizarraga - Study Coordinator
- Kady Bentz - Study Coordinator

POTHOSPLANT
POTHOS

22 January 2017

Via Email

Dr. Sue Sisley
Scottsdale Research Institute
1225 W. Deer Valley Rd.
Phoenix Arizona, AZ 85027

Re: Form 357, Cannabis Product and Services Commitment Letter

Dear Dr. Sisley,

We are very pleased to express our desire to assist with your research and development of cannabis therapies for PTSD. In particular, we are very interested to explore a relationship to develop and to provide stable varieties and cultivars of medicinal Cannabis via Tissue Culture.

Perfect Plants is a mature cultivation company in the Westlands region of the Netherlands with more than 35 years of experience in the commercial cultivation industry. We have more than 600,000 sq. ft. of production facilities in Netherlands and South Africa, and commercial partners in every major market in the world.

We have recently been granted a permit by the BMC in the Netherlands to apply our knowledge and experience to Medicinal Cannabis, with the Dutch Ministry of Health via the BMC as our commercial partners.

We look forward to learning more about your program and plans. We wish to explore how we may work together to ensure a consistent standard of material for your research, and a similar high standard for all aspects of the industry moving forward. We place a tremendous value in working with strong partners in all aspects of our business. We have built our business and infrastructure on such relationships and we look forward to developing such a relationship with you, your organization and your commercial partners.

Please let me know if you require any further information.

Yours Truly,

Perfect Plants B.V.
Peter Olsthoorn, Managing Director

DRAFT - CONFIDENTIAL

better™
MEDICAL GRADE CANNABIS

Attn: Dr. Sue Sisley, M.D.
(480) 326-6023

RE: Cannabis Product and Services Commitment letter for Form 357, January 5, 2017

To Whom It May Concern,

We appreciate the opportunity to collaborate in your research treating Post-Traumatic Stress Disorder with specific Cannabis varieties. For over 9 years we have been operating under the Ministry of Health of Israel's Medical Cannabis Program. Our standardized production and processing protocols produce premium quality, consistent, organic Medical Grade Cannabis. Our R&D continuously develops unique strains to address a variety of medical needs.

Because we started in Israel, all of our Research, Development, Production and Distribution have been legally sanctioned and vetted within a sophisticated research and product validation environment. Cann is one of the only organic, chemical free, international producers of Medical Grade Cannabis with specialized varieties to meet most medical or research needs. Cann has gained invaluable experience as one of the first and largest licensed producers.

Our commitment to medically efficacious and organic production reflects in our products' exceptional quality, consistency, effectiveness and safety developed through years of experience.

In addition to our abilities to provide quantities of specific varieties, we are also prepared to discuss a services agreement, wherein we will build and manage a research cultivation facility for your specific needs.

Our leadership team is a seasoned group of successful executive managers from both the public and private sectors including multiple global product and service organizations. They bring superior knowledge and understanding in navigating cooperation agreements as described herein. We look forward to the next steps in entering a definitive agreement.

Sincerely,

Avi Zur
Chief Operating Officer

Cann Pharmaceutical Ltd,
Tel Aviv 6114401, Israel Tel. +972 (0) 3 635 5101

20 January 2017

Via Email

Dr. Sue Sisley
Scottsdale Research Institute
1225 W. Deer Valley Rd.
Scottsdale, AZ 85027

Re: Form 357, Cannabis Product and Services Commitment Letter

Dear Dr. Sisley:

We are very pleased to offer our evolving Canadian medical cannabis platform to assist with your research and development of cannabis therapies for PTSD, including the provision of genetics/seeds.

In addition to being one of the founders of True Health Co., I serve as its COO and Master Grower, working closely with True Health's scientific team headed by Dr. Scott McKinley.

As you know, True Health Co. is currently constructing a state of the art, federally licensed medical cannabis facility in Powell River, British Columbia, under the strict requirements imposed by Health Canada. Upon full completion, we expect to have over 200,000 square feet of indoor grow, hybrid greenhouse grow, extraction and R&D labs and administrative space under management dedicated to the cultivation of dozens of cannabis strains, together with the extraction of various derivative products, and the manufacturing of a variety of product lines geared to specific medical conditions. We have already received a pre-approval notification from Health Canada. Once we receive our final license approval from Health Canada, we will work with the Scottsdale Research Institute to apply for all the proper DEA permits to legally transport genetics to the U.S.

We are very much looking forward to developing plans with you to construct a new lab within our facility dedicated to meeting your specific requirements to supply appropriate seed strains and FDA approved testing product.

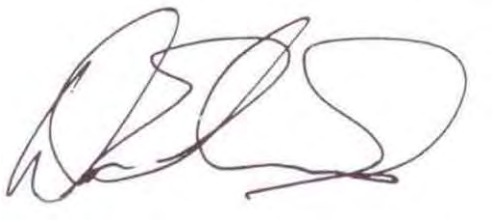
In conjunction with True Health Co., I currently manage the cultivation operations for numerous federally licensed growers and patients under Canada's MMAR (Medical

Marijuana Access Regulations) Program. I have worked in the cannabis field utilizing and developing proprietary genetic strains for over 25 years, and marrying them with unique nutrient profiles to generate individualized treatment options and solutions.

We are in a position to supply you with any needed cannabis genetics/seeds from our federally licensed operations as soon as all the DEA Schedule I license/permitting has been approved.

Please let me know if you require any further information.

Yours Truly,



Donovan Edwards
Master Grower & COO

xMed21, s.r.o.
Osadní 799/26
Praha 7, 17000
Czech Republic

RE: Hemp seed commitment letter for Form 357 January 16, 2017

To Whom It May Concern,

We are an established Industrial Hemp processing company licensed in the Czech Republic (Member State of EU). We purchase EU licensed industrial hemp seed strains and grow them on licensed farms around the Czech Republic. We work in close cooperation with the Czech Academy of Sciences to research and develop new technology and standards for identifying and isolating chemicals derived from specific strains of Cannabis Sativa L.

We are able to source and deliver EU Certified Hemp Seed strains for Scottsdale Research Institute (SRI), including full documentation and certification where appropriate. Our team of experienced scientists and senior managers ensures our cooperation will meet the professional standards needed for successful cooperation with SRI and governing entities during this and future projects. We are currently waiting on SRI's Purchase Order for strains as needed for 2017/2018.

Sincerely,

xMed21 s.r.o.
sadní 799/26, 170 00 Praha 7
: 02672588, DIČ: CZ02672588

Jan Storch, PhD
CEO

From: "Singh, Hari (NIH/NIDA) [E]" <hsingh1@nida.nih.gov>
Date: April 17, 2014 at 7:33:53 AM MST
To: 'Rick Doblin' <rick@maps.org>
Cc: "Gust, Steve (NIH/NIDA) [E]" <sgust@nida.nih.gov>, "Rutter, Joni (NIH/NIDA) [E]" <jrutter@nida.nih.gov>, "Rapaka, Rao (NIH/NIDA) [E]" <rrapaka@nida.nih.gov>, "Gormley, Kevin (NIH/NIDA) [C]" <kgormley@nida.nih.gov>, "Weiss, Susan (NIH/NIDA) [E]" <sweiss@nida.nih.gov>, "Sue Sisley, M.D." <SueSisley@aol.com>, Amy Emerson <amy@maps.org>, "Martin Lee" <aciddreamer@gmail.com>, "Singh, Hari (NIH/NIDA) [E]" <hsingh1@nida.nih.gov>
Subject: RE: Inquiry about Availability and Costs of Marijuana for MAPS study MJP-1

Dear Dr. Doblin:

First, I thank you very much for suggesting to contact Mr. Martin Lee of Project CBD to obtain high CBD clones for the NIDA project as a donation from him. In this respect I will contact Dr. ElSohly and inform him to contact Mr. Martin.

Second, the NIDA Plant Material Inventory currently has very limited supply (couple of hundred gram) of bulk marijuana containing 4.92% CBD and 4.43% THC. However the NIDA contractor at the University of MS (Dr. ElSohly) has been authorized to produce high CBD and low THC variety of marijuana. Thus he is in the process now. On other hand we should be able to meet your need for other marijuana variety containing about 0%, 6%, and 12% THC.

If you have any further question or suggestion, please contact me.

Best wishes,

Hari

Hari H. Singh, Ph.D.
Program Director
Drug Supply & Analytical Services
Chemistry & Physiological Systems Research Branch
Division of Basic Neuroscience & Behavior Research
National Institute on Drug Abuse
National Institutes of Health
6001 Executive Boulevard, Room # 4282, MSC 9555
Bethesda, MD 20892-9555
Phone: (301) 435-1310
Fax: (301) 594-6943
e-mail: hsingh1@nida.nih.gov

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RS0496225	02-28-2017	$244

SCHEDULES	BUSINESS ACTIVITY	DATE ISSUED
1	RESEARCHER (I)	04-19-2016

SISLEY, SUZANNE A.
SCOTTSDALE RESEARCH INSTITUTE
1225 W. DEER VALLEY ROAD
PHOENIX, AZ 85027

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON, D.C, 20537

Sections 304 and 1008 (21 U.S.C. 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
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1	RESEARCHER (I)	04-19-2016

SISLEY, SUZANNE A.
SCOTTSDALE RESEARCH INSTITUTE
1225 W. DEER VALLEY ROAD
PHOENIX, AZ 85027

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Form DEA-223 (05/04)

U.S. DEPARTMENT OF JUSTICE ★ DRUG ENFORCEMENT ADMINISTRATION

DIVERSION CONTROL DIVISION

DEA Registration Validation Result:

DEA Number: BS5887255

This DEA Number is ACTIVE

Name (Last, First): SISLEY , SUZANNE ARLENE MD

Business Activity: PRACTITIONER-DW/100

Business Address 1: (TELEMEDICINE)

Business Address 2: 12622 N. 81ST STREET

Business Address 3:

City: SCOTTSDALE

State: AZ

Zip: 852605232

Schedules: Schedule II Narcotic, Schedule II Non Narcotic, Schedule III Narcotic, Schedule III Non Narcotic, Schedule IV, Schedule V

Fee Status: Paid

Expire Date: 02-28-2019

The U.S. Department of Justice, Drug Enforcement Administration, Diversion Control Division maintains registrant data and is considered the primary source of information on DEA registrants. The website https://www.deadiversion.usdoj.gov is the official location for real time online verification.

December 22nd 2016
Dr. Sue Sisley
suesisley@aol.com
480-326-6023

Digamma Consulting

Dr. Sisley,

Savino and I have put together some basic documents for you outlining the possible costs associated with an analytical cannabis laboratory. This laboratory would include analysis of cannabinoids, terpenes, and microbiological contamination. Cannabinoid analysis would be performed by High Performance Liquid Chromatography Photo Diode Array (HPLC-PDA), terpene analysis would be performed by Head Space Gas Chromatography Mass Spectrometry (GCMS), and micro would be tested by growth medium. Agarose would be used for Total Yeast and Mold (TYM) analysis, and aerobic and coliform bacteria would be tested on 3M Petrifilms.

For optimum performance, we would recommend the following instruments purchased new:

HPLC-PDA	Waters Acquity System
GCMS	PerkinElmer Clarus 680 / SQ8 / TurboMatrix40

For minimal cost, we have provided an assessment of the cost of the relevant equipment available in used condition. In an attached document called "**Dr Sisley Equipment List 2016-12-22**" we outline the range in cost for each instrument, including a lowest price, median, highest price, and statistical range of prices within one standard deviation.

To consider the cost of consumables, we have reviewed the relevant price to the laboratory for each sample analyzed. The attached document "**Dr Sisley Consumables 2016-12-22**" outlines the cost of each purchasable unit and the amount consumed per sample analyzed.

Please let us know if you have any further questions.

Sincerely,

Marco Troiani
Digamma Consulting
marco@digammaconsulting.com
617-669-8748

Savino Sguera
Digamma Consulting
savino@digammaconsulting.com

Cannabis Analysis Laboratory Cost Projections - Consumables

Item Name	Estimated Cost / Package	Units / Package	Units / Sample	Estimated Cost / Sample
Solvent and Terpenes				
22 ml headspace vials	$35.00	100	2	$0.70
isopropanol, GC grade	$146.00	4000	0.1	$0.00
STD: Terpenes + Terpeneols	$220.00	1000	1	$0.22
STD: Terpene Oxides	$40.00	1000	1	$0.04
Nitrile Gloves	$56.77	1000	2	$0.11
2 ml chromovials	$208.50	1000	0.1	$0.02
acetone, GC grade	$229.00	5000	0.1	$0.00
STD: propane, 1 ml	$31.00	1000	7	$0.22
STD: butane, 1 ml	$31.00	1000	7	$0.22
STD: isobutane, 1 ml	$36.00	1000	7	$0.25
Total				$1.79
Terpenes				$1.10
Solvents: All				$1.53
Solvents: Propane Only				$1.06
Cannabinoids				
15 ml conical vials	$263.00	500	1	$0.53
methanol, LC grade	$213.31	16000	20	$0.27
water, LC grade	$212.06	16000	5	$0.07
acetone, LC grade	$229.00	5000	1	$0.05
0.2 um PTFE filters	$231.84	100	1	$2.32
Filter syringe, disposable	$14.65	100	1	$0.15
2 ml chromovials	$208.50	1000	3	$0.63
Pipet Tips, 1000 uL	$32.50	1000	1	$0.03
Pipet Tips, 100 uL	$158.16	960	2	$0.33
Nitrile Gloves	$56.77	1000	2	$0.11
STD: d9-THC, 1 ml	$25.00	1000	1	$0.03
STD: CBD, 1 ml	$25.00	1000	1	$0.03
STD: THCA, 1 ml	$159.00	1000	1	$0.16
STD: CBDA, 1 ml	$169.00	1000	1	$0.17
STD: CBN, 1 ml	$25.00	1000	1	$0.03
STD: CBG, 1 ml	$155.00	1000	1	$0.16
STD: CBGA, 1 ml	$169.00	1000	1	$0.17
STD: CBC, 1 ml	$109.00	1000	1	$0.11
STD: d8-THC, 1 ml	$25.00	1000	1	$0.03
STD: THCV, 1 ml	$195.00	1000	1	$0.20
STD: CBDV, 1 ml	$165.00	1000	1	$0.17
STD: CBDVA, 1ml	$199.00	1000	1	$0.20
STD: CBL	$189.00	1000	1	$0.19

Cannabis Analysis Laboratory Cost Projections - Consumables

Item Name	Estimated Cost / Package	Units / Package	Units / Sample	Estimated Cost / Sample
Total (13 cannabinoids)				$6.08
THC only				$4.50
THCA and THC only				$4.65
THC, CBD, THCA, CBDA				$4.85
THC, CBD, CBG + Acids				$5.17
Microbiologicals				
Agar Plates TYM	$23.25	10	3	$6.98
Sterile Petri Dish	$89.00	500	3	$0.53
Sabaroud Dextrose Agar	$70.50	500	4	$0.56
Petrifilm Aerobic Bacteria	$70.50	50	3	$4.23
Distilled Water	$32.18	10000	10	$0.03
Buffered Peptone	$227.00	500	0.56	$0.25
Nitrile Gloves	$56.77	1000	2	$0.11
Sterile Spreader	$31.25	100	1	$0.31
Stomacher Bags	$116.00	500	1	$0.23
Pipet Tips, 1000 uL	$32.50	1000	2	$0.07
Pipet Tips, 100 uL	$158.16	960	1	$0.16
Pipet Tips, 10 mL	$28.50	100	0.1	$0.03
10 ml sterile tubes	$78.38	500	4	$0.63
Denatured Alcohol	$4.47	946	3	$0.01
Yeast and Mold (purchased plates)				$8.82
Yeast and Mold (in-house plates)				$2.94
Aerobic Bacteria				$5.60
Total (purchased plates)				$13.05
Total (in-house plates)				$7.17

Cannabis Analysis Laboratory Cost Projections - Used Analytical Instruments

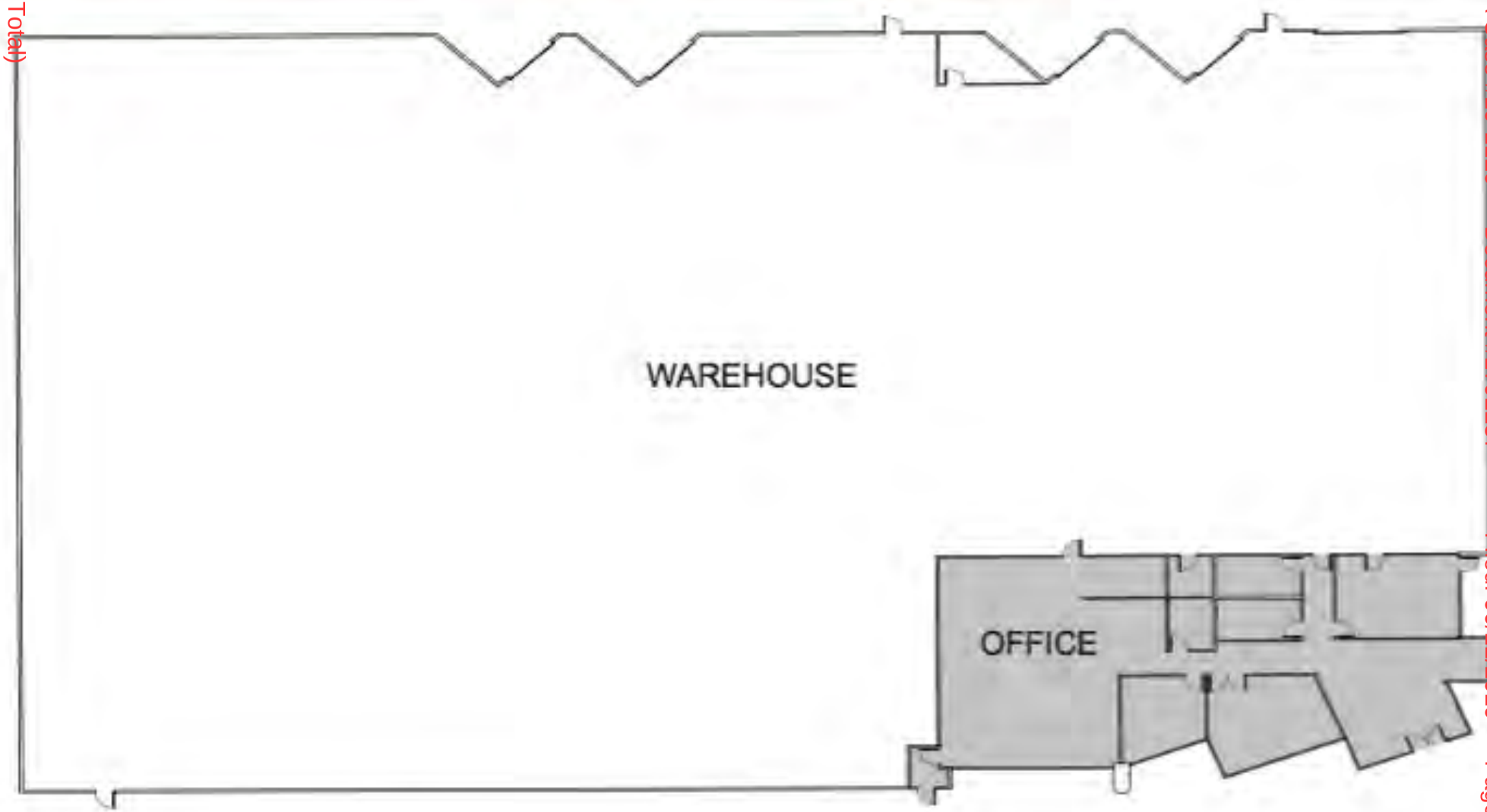
Item Name	Low	Median	High	Statistical Range		
Solvent and Terpenes						
GCMS System	$2,500.00	$16,000.00	$48,500.00	$6,135.77	-	$31,111.99
Headspace Sampler	$2,200.00	$2,757.00	$7,999.00	$1,644.42	-	$6,539.59
Desktop Computer	$124.27	$218.94	$439.99	$147.36	-	$340.87
Hamilton Syringe, 10 uL	$54.00	$54.00	$54.00	$54.00	-	$54.00
Hamilton Syringe, 500 uL	$56.00	$56.00	$56.00	$56.00	-	$56.00
Total	$4,934.27	$19,085.94	$57,048.99	$8,037.55	-	$38,102.45
Terpenes Only						
GC Oven	$500.00	$6,500.00	$34,000.00	$1,421.46	-	$14,800.72
Headspace Sampler	$2,200.00	$2,757.00	$7,999.00	$1,644.42	-	$6,539.59
Desktop Computer	$124.27	$218.94	$439.99	$147.36	-	$340.87
Hamilton Syringe, 10 uL	$54.00	$54.00	$54.00	$54.00	-	$54.00
Hamilton Syringe, 500 uL	$56.00	$56.00	$56.00	$56.00	-	$56.00
Total	$2,934.27	$9,585.94	$42,548.99	$3,323.24	-	$21,791.18
Cannabinoids						
UPLC-PDA	$4,000.00	$19,750.00	$42,000.00	$11,371.67	-	$29,839.99
Tissue Homogenizer	$176.40	$741.43	$1,130.06	$176.40	-	$1,130.06
Sonicator	$119.95	$331.20	$830.00	$134.98	-	$659.71
Pipetor, 10-100 uL	$129.00	$212.50	$279.00	$136.40	-	$273.47
Pipetor, 100-1000 uL	$129.00	$279.00	$370.00	$13,946.00	-	$352.54
Desktop Computer	$124.27	$218.94	$439.99	$147.36	-	$340.87
Total	$4,678.62	$21,533.07	$45,049.05	$25,912.81	-	$32,596.64
Microbiologicals						
HEPA filtered Bio-Hood	$1,995.00	$4,549.00	$10,612.95	$2,559.92	-	$9,297.48
Incubator	$750.00	$1,999.00	$5,299.00	$1,258.68	-	$4,280.22
Autoclave	$102.96	$334.00	$899.00	$163.58	-	$730.27
Total	$2,847.96	$6,882.00	$16,810.95	$3,982.18	-	$14,307.97

Digamma Consulting

Savino Sguera Marco Troiani

FLOOR PLAN

15550 NORTH 78TH STREET
SCOTTSDALE, AZ 85260

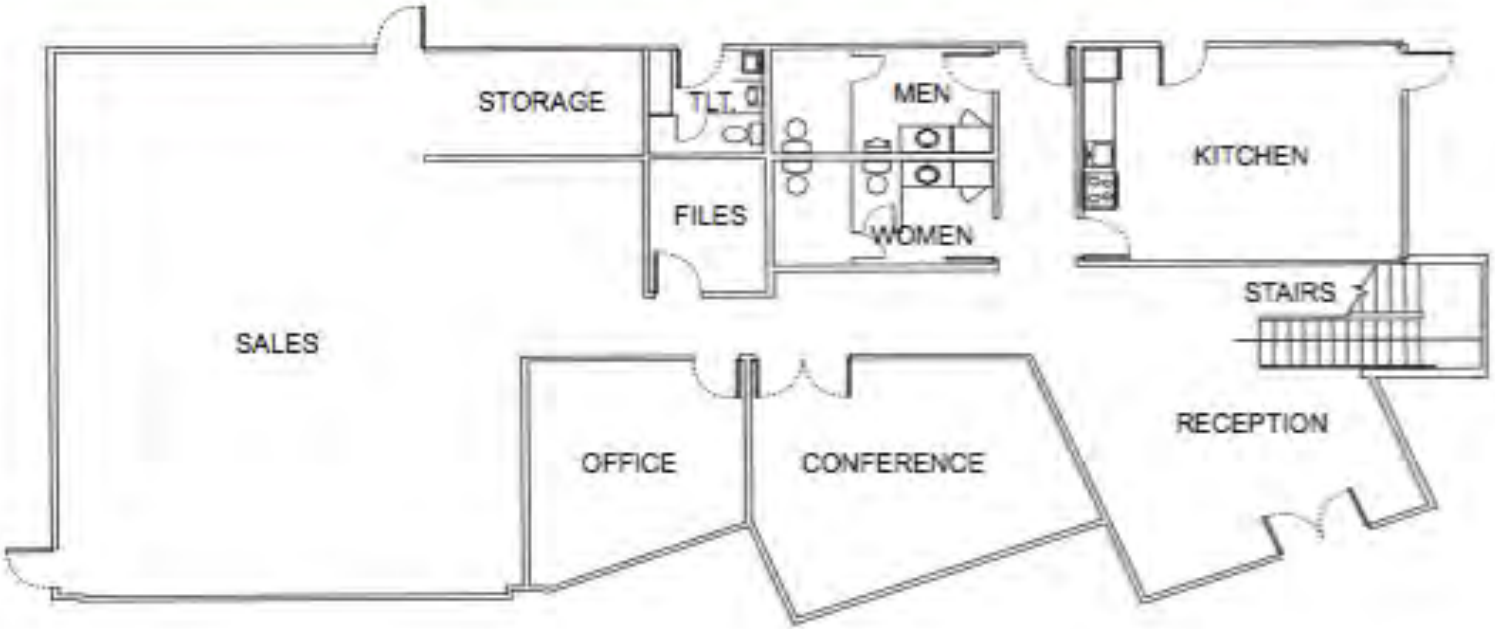


SQUARE FOOTAGE SUMMARY

- Warehouse: 31,450 SF
- Office: 3,627 SF

FLOOR PLAN

15550 NORTH 78TH STREET
SCOTTSDALE, AZ 85260



SQUARE FOOTAGE SUMMARY

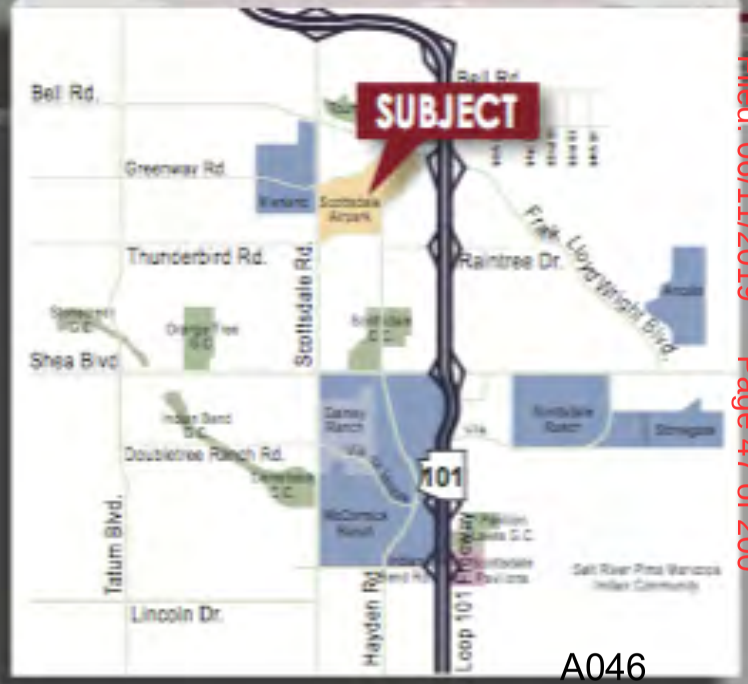
- Office: 3,627 SF
- Mezzaine: 4,149 SF (concrete deck unfinished)

A045

15550 NORTH 78TH STREET

SCOTTSDALE , ARIZONA 85260

15550 North 78th Street is a Class B industrial manufacturing building that was built in 1995. This 39,226 SF building on 2.0 acres allows buyers to take avantage of an existing facility in the heart of the Scottsdale Airpark and located just west of the 101 Freeway and Greenway/Hayden Loop.



PROPERTY FEATURES

- Total site: 2 acres
- Existing building: 39,226 SF
- Office: 3,627 SF
- Warehouse: 31,450 SF
- Mezzanine: 4,149 SF concrete deck unfinished
- Clear height: 22' - 24'
- 4 dock high doors (in place pit levelers w/electrical feed)
- 1 drive in door (8'w x 10'h)
- Truck court depths: 44' - 81'
- Clearspan building
- Fully sprinklered
- Fully air conditioned
- 24 covered parking
- Secured site with wrought iron gates
- Concrete tilt consturction
- Metal roof
- T-5 lighting
- Year Built: 1995
- Scottsdale Airpark, 5 minutes to Loop 101
- Zoning: I-1 Light Industrial

IEWC

Building

Type	3 Star Industrial Warehouse		
RBA	40,000 SF	Year Built	1980
Stories	1	Year Renov	Feb 2014
Typical Floor	40,000 SF	Tenancy	Single
Class	C	Owner Occup	Yes
Docks	None	Ceiling Ht	16'-18'
Drive Ins	3 tot./8'w x 10'h	Elevators	None
Cross Docks	None	Rail Spots	None
Levelators	None	Cranes	None
Construction	Reinforced Con…		
Building Ht	25'		
Truck Wells	None		

Property Mix	Industrial	38,000 SF	95.0%
	Office	2,000 SF	5.0%

Power	2,000a/480v Heavy
Parking	114 free Surface Spaces are available; 6 free Covered Spaces are available; Ratio of 3.00/1,000 SF
Taxes	$0.55/SF (2016)
Opex	$0.48/SF (2012-Est)
Walk Score®	Car-Dependent (26)
Transit Score®	Some Transit (35)

Land

Land Acres	3.20 AC	Land SF	139,392 SF
Bldg FAR	0.29		
Zoning	A-1, Phoenix		
Parcel	209-09-026A		

EXHIBIT 3

Schedule I & II
Bulk Manufacturers
& Importers

Drug Enforcement Administration
Pharmaceutical Training Seminar

Philadelphia, PA
April 12 – 15, 2016

San Antonio, TX
April 25– 28 2016

Persons Required to Register

- Law: 21 USC 822 (a) (1)
- "Every person who manufactures or distributes any controlled substance or list I chemical …shall obtain … a registration…

Persons Required to Register

- Law: 21 USC 822 (a) (2)

- "Every person who dispenses, or who proposes to dispense, any controlled substance, shall obtain from the Attorney General a registration…"

Registrations

- Manufacturer
- Distributor
- Importer
- Exporter
- Pharmacy
- Practitioner
- Researcher, NTP, Analytical Lab, Teaching Institution

Manufacturers

- Bulk Manufacturers
- Dosage Form Manufacturers
- Manufacturers Who Re-Package/Re-Label

Specific Registrations

- Bulk Manufacturers
  CI or CII Controlled Substances

- Importers
  CI or CII Controlled Substances

Legal Definition 21 USC 802

The term **Bulk Manufacturer** means: the production, preparation, propagation, compounding, or processing of a drug or other substance, either directly or indirectly or by extraction from substances of natural origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis,

In Plain English

Produces the bulk controlled substance used for the preparation of saleable dosage units.

Synthesizer: Produces CS raw materials from basic chemicals.

Extractor: Derives a drug from an organic source. All narcotics are manufactured through extraction. Companies import raw material (Raw Opium/Cocoa Leaf) and extract the active ingredients which are the starting point for the further production of a variety of drugs.

Importers

For purposes of this presentation, CI and CII importation applies ***only to*** Importer registrations and ***not to*** coincidental activities which are authorized for researcher and analytical laboratory registrations pursuant to 21 C.F.R. § 1301.13 (e) (1).

"Section 303"

On October 27, 1970, Section 303 was passed into law by Congress.

303 was the number used by Congress to track the legislation.

Once passed by Congress, Section 303 was placed into 21 USC 823.

Therefore: "Section 303 Investigations"
"Section 303 Registrants"

Legal Citations
United States Code

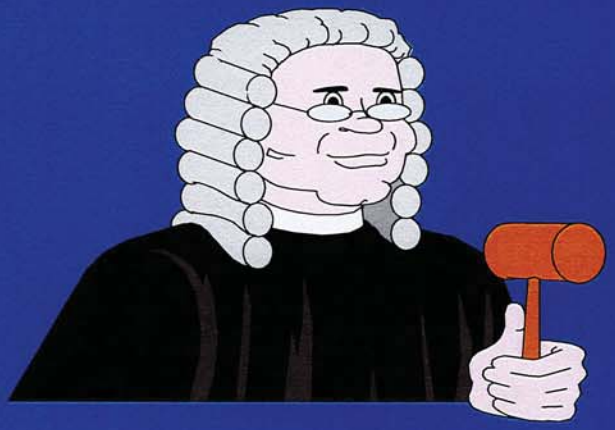
- 21 USC 823(a)

Legislates the registration of CI & CII bulk manufacturers and includes the six (6) "public interest" factors which must be examined and considered prior to granting the registration.

The Denial of A Registration

- 21 USC 824

Legislates the conditions under which a registration to manufacture, distribute, or dispense a controlled substance may be denied, suspended, or revoked.



Legal Citations
United States Code

- 21 USC 958

Legislates the Registration and/or Denial of CI & CII Importers.

Code of Federal Regulations

- 21 C.F.R. § 1301.33 (Manufacturers)
- 21 C.F.R. § 1301.34 (Importers)

- Establishes the regulations which govern the approval and renewal processes for CI & CII bulk manufacturer and importer applications.

Activity which is *NOT* allowed

DEA grants Importer registrations and allows the importation of CI & CII controlled substances to "provide for the medical, scientific, or other legitimate needs **of the United States**." 21 USC 952(a)(2).

The statute does not allow an importer to import a CI or CII controlled substance for the purpose of exporting it.

Importation is authorized only for its domestic use in the United States.

21 USC 823
Registration Requirements

Manufacturers of controlled substances in Schedule I and II

(a) The Attorney General shall register an applicant to manufacture controlled substances in Schedule I or II if he determines that such registration is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971.

In determining the public interest, the following factors shall be considered:

21 USC 823
Registration Requirements

Manufacturers of controlled substances in Schedule I and II

1) Maintenance of effective controls against diversion of particular controlled substances and any controlled substance in Schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes;

21 USC 823
Registration Requirements

2) Compliance with applicable State and local law;

3) Promotion of technical advances in the art of manufacturing these substances and the development of new substances;

4) Prior conviction record of applicant under Federal and State laws relating to the manufacture, distribution, or dispensing of such substances;

21 USC 823
Registration Requirements

5) Past experience in the manufacture of controlled substances, and the existence in the establishment of effective control against diversion; and

6) Such other factors as may be relevant to and consistent with the public health and safety.

"The 303 Process"

The Section 303 Process is initiated upon receipt by DEA Headquarters of a

-New Application for Registration

-Renewal Application

-Request to Modify a Registration

The Review Includes:

- DEA Field Investigation

- DEA HQs Analysis and Review

- Publication in the Federal Register

- And any other additional information as deemed necessary (21 C.F.R. § 1301.15)

Reviewing the Application

- The review process is required to ensure compliance with the requirements of
  21 C.F.R. §§ 1301.33 and 1301.34.

- The DEA field office does not have the authority to approve or modify a registration subject to a 303 investigation.

- In regards to a Section 303: A request to add a new drug code is considered an "application."

Processing the Application

1) Application forms are submitted to the Registration Section at DEA headquarters.

2) The Registration Section processes the fees and reviews the application for completeness.

3) If it is a new application (as a Bulk Manufacturer or an Importer) the Registration Unit places it in a "Pending/Hold" status.

Processing the Application (continued)

4) The application is then forwarded to the Regulatory Section for processing under the Section 303 (21 USC 823) guidelines.

5) Upon receipt of the new or renewal application from the Registration Unit, or upon the receipt of a written request to add a drug code, the Staff Coordinator/Program Analyst reviews the application. If it is a renewal application, the drug codes are compared to those for which the registrant is already authorized.

Processing the Application (continued)

6) If the renewal application contains new drug codes, or if the application is for a new registration, the Staff Coordinator or Program Analyst will contact the firm by fax to obtain responses to the standardized *Bulk Manufacturer Questions* or *Importer Questions*.

The questions are incorporated at the end of this presentation.

Processing the Application (continued)

7) After the registrant responds to the questions, the responses, and all of the results from the investigation and analysis, are reviewed by various sections at DEA HQs.

When all sections have found no legal (public interest) reason to deny the application, a Notice of Application is prepared for signature by the Deputy Assistant Administrator, Office of Diversion Control. Once signed, the Notice is transmitted to the Office of the Federal Register for publication.

Processing the Application (continued)

8) The CFR requires a comment period during which other bulk manufacturers of the same basic classes of controlled substances can file comments and objections to the proposed registration.

The comment period for CI & CII bulk manufacturer registrations is 60 days. For CI & CII importers it is 30 days. The comment period commences the date the Notice of Application is published in the Federal Register.

Processing the Application (continued)

9) With the preparation of the Notice of Application, an electronic investigative tasking has already been sent to the DEA field division office responsible for the applicant/registrant.

The field office will conduct an investigation of the applicant/registrant which includes the six public interest factors in 21 USC 823 (a)(1-6).

A report must be written and submitted to the Regulatory Unit as part of the review process on the application.

Processing the Application (continued)

10) When the comment period for the Notice of Application closes, the Staff Coordinator or Program Analyst will determine whether or not any comments or objections to the proposed registration were received.

Processing the Application (continued)

11) If **NO** comments or objections have been received, and if the review process of the applicant's request has been completed by DEA, and found to be consistent with the public interest and with the United States obligations under international treaties, then a Notice of Registration will be prepared for the Deputy Assistant Administrator's signature. Once signed, it will be transmitted to the Office of the Federal Registrar and published.

IMPORTER QUESTIONS
CI & CII CONTROLLED SUBSTANCES
(continued)

13) Do you currently have any other controlled substance registrations from the Drug Enforcement Administration? If so, please provide the registration number(s), business activity, drug schedules, and expiration date.

Regulatory Unit (ODGR)

Abby Hayes, Acting Unit Chief/ODGR
Phone (202) 307-8910
Abby.F.Hayes@usdoj.gov

Marquita Brown, Program Analyst
Phone (202) 353-1199
Marquita.L.Brown@usdoj.gov

Fax number (202) 307-8101

Registration Unit (ODRR)
1-800-882-9539

Completion of the Process

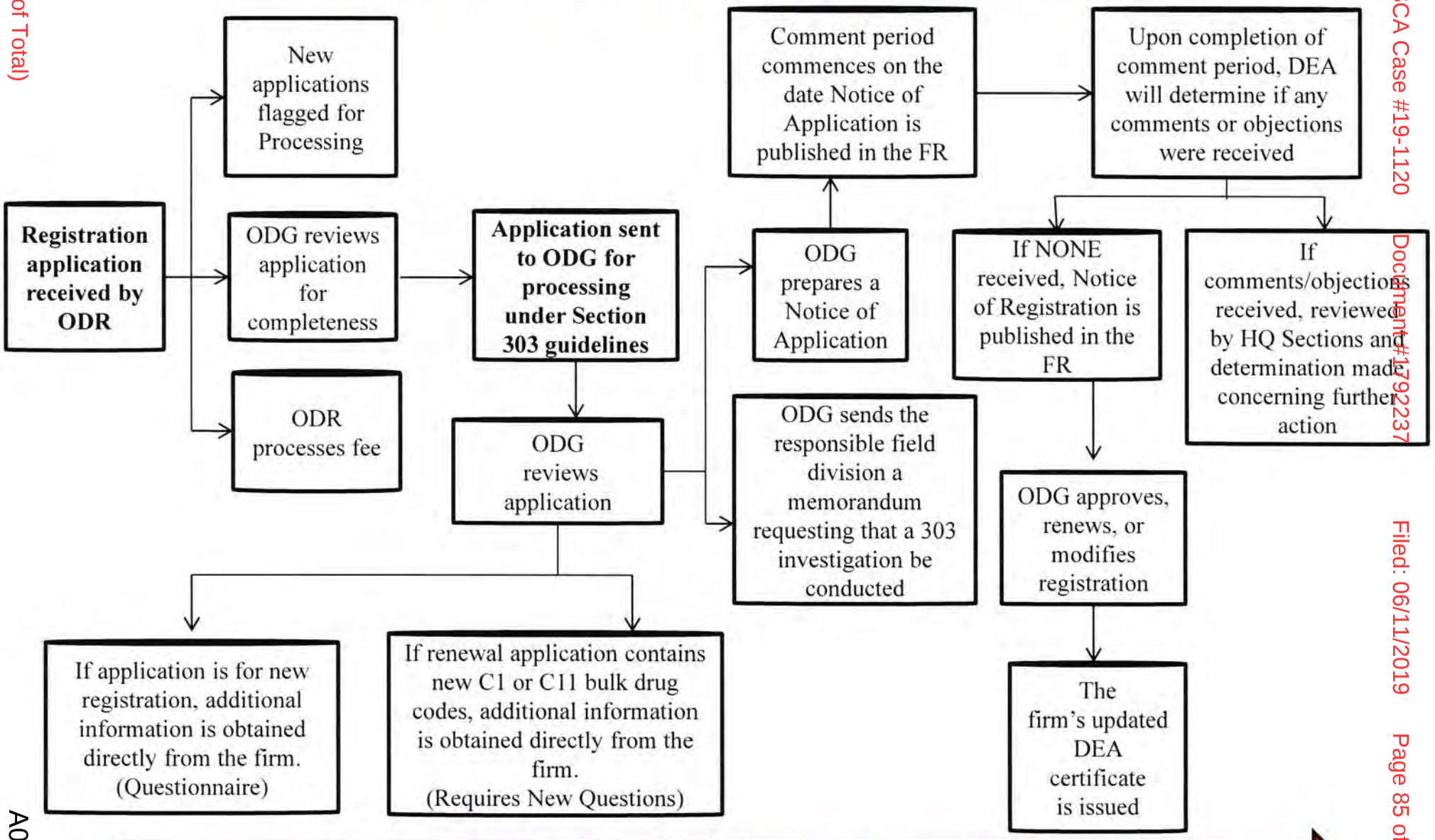
When the Notice of Registration is published, the Staff Coordinator notifies the Registration Unit and asks that the action on the application be completed. The Registration Unit then makes any modifications which have been requested, and renews the application.

The registrant's updated DEA certificate is electronically generated and mailed.

THIS IS A ***PROCESS***, NOT A ***SINGLE ACTION***.
IT IS NOT UNCOMMON FOR
THIS PROCESS TO TAKE 4-6 MONTHS TO
COMPLETE.

PLEASE CONTACT THE STAFF COORDINATOR OR PROGRAM ANALYST IF YOU NEED AN UPDATE ON THE STATUS OF YOUR APPLICATION/
REQUEST.

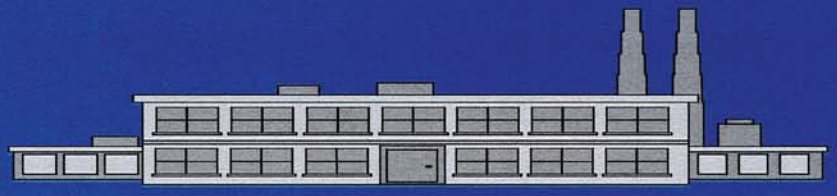
Processing 303 Applications



ODG-Regulatory Section
ODR-Registration Section

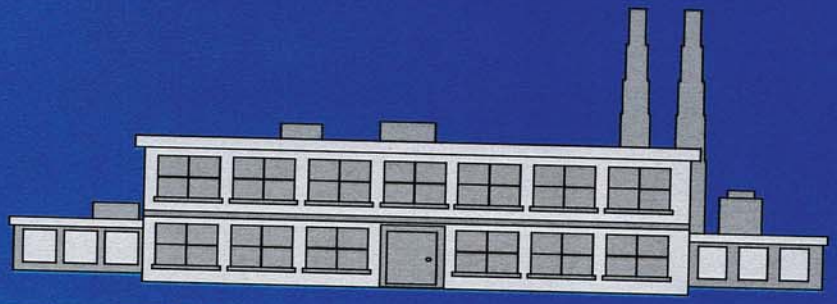
INDUSTRY EFFORTS THAT HELP KEEP THE PROCESS MOVING

- ✓ Maintain copies of your application(s) and all other documents for registration and renewal.
- ✓ Review your applications before you mail them.
- ✓ Check √ (Circle) the drug codes you intend to manufacture in bulk as requested on the application. DEA will *not* presume you want the same codes that you previously requested. If the codes are not Checked (Circled), they will not be included on the FR Notice.



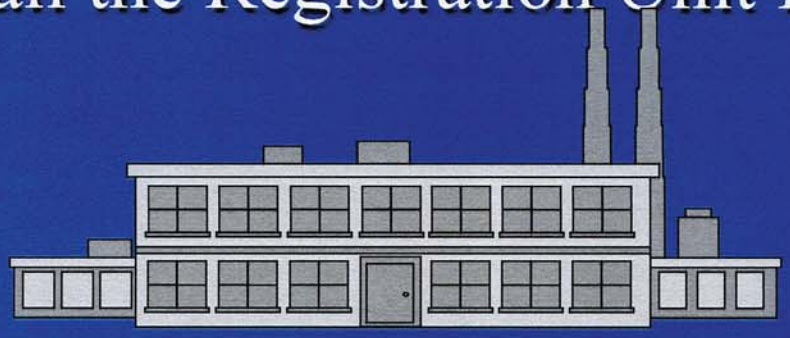
INDUSTRY EFFORTS THAT HELP KEEP THE PROCESS MOVING

- ✓ Include all drug codes pending approval on your renewal application.
- ✓ Retain a copy of the Importer and Bulk Manufacturer Questions. When you have complete responses to the questions, you will know the time is right to request that the drug code(s) be added to your registration.



INDUSTRY EFFORTS THAT HELP KEEP THE PROCESS MOVING

- ✓ Submit your Application/Request ASAP
- ✓ Applications are mailed out 120 days in advance of the expiration date. Applications can also be completed on-line 120 days in advance of the expiration date.
- ✓ Be aware of the expiration date(s) on your registrations. If the expiration date is nearing (or has passed) and you have not received a renewal application, call the Registration Unit for assistance.



INDUSTRY EFFORTS THAT HELP KEEP THE PROCESS MOVING

- ✓ If your registration has expired, and you have submitted a renewal application, you may contact the Staff Coordinator or Program Analyst and request an "extension letter" that you can provide to your suppliers and customers for verification purposes or
- ✓ E-mail or fax a copy of your application to ODGR/Regulatory Unit/DEA Headquarters
- ✓ E-mail or fax a copy of your responses to our questions about your Manufacturer/Importer registration.

21 C.F.R. § 1301.36 (i)

BULK MANUFACTURER QUESTIONS CI & CII CONTROLLED SUBSTANCES

The following questions pertain to your company's request to bulk manufacture CI and/or CII controlled substances (CS).

Please provide detailed responses to the following questions for <u>each</u> drug code that your company has proposed to manufacture in bulk.

BULK MANUFACTURER QUESTIONS CI & CII CONTROLLED SUBSTANCES

1) What is the purpose for the bulk manufacture of the CS?

2) Specifically describe the production process, from start to finish, for each CS.

3) What materials will be used to manufacture the CS and in what quantities?

BULK MANUFACTURER QUESTIONS CI & CII CONTROLLED SUBSTANCES (CONTINUED)

4) Please provide the name, address, method of shipment and method of delivery for each supplier from which your firm intends to procure materials for the manufacture of the CS.

BULK MANUFACTURER QUESTIONS CI & CII CONTROLLED SUBSTANCES (CONTINUED)

5) Does your company have a firm commitment from each supplier of raw material? What is the time period of this agreement and what quantity of raw material will each supplier be able to supply? **Please attach copies of commitment letters from each supplier.**

6) What quantity of each CS does your company anticipate producing in bulk?

BULK MANUFACTURER QUESTIONS CI & CII CONTROLLED SUBSTANCES (CONTINUED)

7) Who are your current and prospective customers (name/address) for <u>each</u> CS?

A) What product (active pharmaceutical ingredient – API, dosage units, materials for clinical research, etcetera) does your company intend to sell to each customer listed?

B) What quantity of each substance has the customer indicated it would purchase?

BULK MANUFACTURER QUESTIONS CI & CII CONTROLLED SUBSTANCES (CONTINUED)

C) For what purpose would the customers purchase the CS (i.e., dosage form development, clinical trials, drug master file submissions)? Again, please be specific as it relates to each customer and each CS identified above.

Please attach copies of letters of interest from the prospective customers.

BULK MANUFACTURER QUESTIONS CI & CII CONTROLLED SUBSTANCES (CONTINUED)

8) What are your company's future plans with regard to the manufacture of controlled substances? Please provide as much detail as possible, including time line, and discuss any plans to expand your production facility, add new equipment, conduct research and development, run initial batches, and list FDA approvals needed.

BULK MANUFACTURER QUESTIONS CI & CII CONTROLLED SUBSTANCES (CONTINUED)

9) When does your company anticipate selling each of the CS as commercial product?

10) Do you currently have any other CS registrations from the Drug Enforcement Administration? If so, please include the DEA number (s), business activity, drug schedules, and expiration date(s) in your response.

IMPORTER QUESTIONS
CI & CII CONTROLLED SUBSTANCES

The following questions pertain to your request to import CI and/or CII controlled substances (CS).

Please provide detailed responses to the following questions for each CI and/or CII drug code that you (your firm) has requested authority to import.

IMPORTER QUESTIONS CI & CII CONTROLLED SUBSTANCES (continued)

1) What type of CS does your firm intend to import: bulk or dosage units?

2) What is the purpose for the importation of the CS: narcotic raw material for bulk manufacture, clinical trials, research, analytical purposes, distribution.

IMPORTER QUESTIONS
CI & CII CONTROLLED SUBSTANCES
(continued)

3) Why is a foreign source of supply being used instead of a domestic source?

4) What is the name, address, method of shipment and method of delivery for each supplier of CS your company proposes to import?

IMPORTER QUESTIONS
CI & CII CONTROLLED SUBSTANCES
(continued)

5) Does your company have a firm commitment from the supplier/suppliers of each substance proposed for importation?
   a) What is the time period of the commitment?
   b) What quantity is involved?
   c) Letters of Commitment?

6) What quantity of each CS does your company anticipate importing on an annual basis?

IMPORTER QUESTIONS
CI & CII CONTROLLED SUBSTANCES
(continued)

7) Who are your current and prospective customers? Please provide a list of names, addresses, and DEA numbers for each CS.

Please attach copies of letters of intent from these customers.

IMPORTER QUESTIONS
CI & CII CONTROLLED SUBSTANCES
(continued)

8) Will the controlled substances you propose to import be used to manufacture controlled substances? If so, how and in what quantity are they to be manufactured?

9) Does your company have previous experience handling CS? Please Explain.

IMPORTER QUESTIONS
CI & CII CONTROLLED SUBSTANCES
(continued)

10) Does your company have previous experience in the importation of CS? Please explain.

11) When does your company anticipate selling a commercial product?

IMPORTER QUESTIONS
CI & CII CONTROLLED SUBSTANCES
(continued)

12) Please provide a written description of what resources your company has committed to the establishment of your importation business as regards to these drug codes.

Do do you plan to or have you already made any changes to:

- Physical plant
- Security system
- Production equipment
- Recordkeeping system

What is your proposed time frame for completion of those activities?

EXHIBIT 4

Help

12/05/2016
HYATT FISHERMANS WHARF
$255.02
$4,069.17

11/30/2016
DEA REGISTRATION
$3,047.00
$3,814.15

View All

REWARDS

0
Total Points

View/Redeem

CREDIT LINE DETAILS

Cash Balance $0.00

Available Credit for Purchases $19,762.46

Available Credit for Cash Advances $4,900.00

Pending Transactions $59.99

EXHIBIT 5

US Senator Orrin Hatch

Press releases are archived according to their release date. For press releases by topic, please see the Issue Positions page.

Apr 12 2018

Hatch, Harris Call on Sessions, DOJ to Stop Blocking Medical Marijuana Research

"We write to request that you enable the Drug Enforcement Administration (DEA) to fulfill its charter of lawfully registering manufacturers of the controlled substance of marijuana for research without delay. Research on marijuana is necessary to resolve critical questions of public health and safety, such as learning the impacts of marijuana on developing brains and formulating methods to test marijuana impairment in drivers."

Washington, DC—US Senators Orrin Hatch (R-UT) and Kamala Harris (D-CA), both members of the Senate Judiciary Committee, sent a letter today to US Attorney General Jeff Sessions urging the Drug Enforcement Administration (DEA) to cease efforts to slow medical marijuana research, following reports that the Department of Justice was blocking medical marijuana research efforts by delaying approvals for manufacturers growing research-grade medical marijuana.

Expanded research has been called for by President Trump's Surgeon General, the Secretary of Veterans Affairs, the FDA, the CDC, the National Highway Safety Administration, the National Institute of Health, the National Cancer Institute, the National Academies of Sciences, and the National Institute on Drug Abuse. There are currently two bipartisan bills before the Senate Judiciary Committee that would streamline the cumbersome process for researchers to receive federal permission to study marijuana.

"The benefits of research are unquestionable. Research will give law enforcement guidance to do their jobs:protecting drivers on the roads, protecting kids in schools, and maintaining law and order. Ninety-two percent of veterans support federal research on marijuana, and the Department of Veterans' Affairs is aware that many veterans have been using marijuana to manage the pain of their wartime wounds. America's heroes deserve scientifically-based assessments of the substance many of them are already self-administering. By allowing expanded research, the Department of Justice will aid legislators in making sound decisions, help law enforcement in developing critical public safety guidance, and ensure that citizens have the benefit of informed, evidence-based policy."

The full letter is included below:

The Honorable Jeff Sessions

Attorney General of the United States

U.S. Department of Justice

950 Pennsylvania Avenue, N.W.

Washington, D.C. 20540

Dear Attorney General Sessions:

We write to request that you enable the Drug Enforcement Administration (DEA) to fulfill its charter of lawfully registering manufacturers of the controlled substance of marijuana for research without delay. Research on marijuana is necessary to resolve critical questions of public health and safety, such as learning the impacts of marijuana on developing brains and formulating methods to test marijuana impairment in drivers.

To date, it has been federal practice that only one manufacturer — the University of Mississippi — is licensed to produce marijuana for federally-sanctioned research. Historically, as the DEA has noted, that single manufacturer could meet the minimal demand for research. However, the DEA changed its policy nearly two years ago because, as it explained, "There is growing public interest in exploring the possibility that marijuana or its chemical constituents may be used as potential treatments for certain medical conditions," and the DEA — along with the Food and Drug Administration (FDA) and the National Institutes of Health (NIH)

— "fully supports expanding research into the potential medical utility of marijuana and its chemical constituents."

As of August 11, 2016, 354 individuals and institutions were approved by the DEA to conduct expansive research on marijuana and its related components. Those researchers needed access to a federally compliant expanded product line—they needed to study different types of marijuana and across various delivery mechanisms. Accordingly, a diverse, DEA-vetted market of suppliers of research-grade marijuana would be critical. Since the DEA's Federal Register Notice on August 12, 2016, at least 25 manufacturers have formally applied to produce federally-approved research-grade marijuana.

Last August, The Washington Post reported that you have been blocking these efforts: "The Justice Department under Attorney General Jeff Sessions has effectively blocked the Drug Enforcement Administration from taking action on more than two dozen requests to grow marijuana to use in research."

When asked by Senator Hatch at a Judiciary Committee oversight hearing to clarify DOJ's role in processing these applications, you said, "I think it would be healthy to have some more competition in the [federally-approved research-grade marijuana] supply, but I'm sure we don't need 26 new suppliers." Nevertheless, the supply needed for research is clearly not meeting the demand. There are currently two bipartisan bills before the Senate Judiciary Committee that would streamline the obtuse process for researchers to receive federal permission to study marijuana. Those bills and the strong popular support they have received are indicative of the nation's demand for marijuana to be thoroughly researched.

We write this letter because research on marijuana is necessary for evidence-based decision making, and expanded research has been called for by President Trump's Surgeon General, the Secretary of Veterans Affairs, the FDA, the CDC, the National Highway Safety Administration, the National Institute of Health, the National Cancer Institute, the National Academies of Sciences, and the National Institute on Drug Abuse. In order to facilitate such research, scientists and lawmakers must have timely guidance on whether, when, and how these manufacturers' applications will be resolved.

The benefits of research are unquestionable. Research will give law enforcement guidance to do their jobs:protecting drivers on the roads, protecting kids in schools, and maintaining law and order. Ninety-two percent of veterans support federal research on

marijuana, and the Department of Veterans' Affairs is aware that many veterans have been using marijuana to manage the pain of their wartime wounds. America's heroes deserve scientifically-based assessments of the substance many of them are already self-administering.

By allowing expanded research, the Department of Justice will aid legislators in making sound decisions, help law enforcement in developing critical public safety guidance, and ensure that citizens have the benefit of informed, evidence-based policy.

Nineteen months have elapsed since the DEA announced its request for expanded marijuana research. To ensure that the DOJ resolves these applications in a timely fashion, allowing the DEA to fulfill its charter, we request that by May 15, 2018, you provide:

- *Notice of the date that the Department of Justice expects to complete its review of these applications so that the DEA may grant these new suppliers a license to produce marijuana for federally approved research;*

- *Notice to applicants of the timeline for resolution and the status of their applications;*

- *Notice of actions you have taken to review applications since October 18, 2017, when you testified before the Judiciary Committee that competition among federally-approved marijuana producers would be "healthy;" and*

- *A commitment to resolve applications by August 11, 2018, at the latest (exactly two years since the DEA announced its policy change).*

Permalink: https://www.hatch.senate.gov/public/index.cfm/2018/4/hatch-harris-call-on-sessions-doj-to-stop-blocking-medical-marijuana-research

EXHIBIT 6

Congress of the United States
Washington, DC 20510

August 30, 2018

The Honorable Robert Wilkie
Secretary of Veterans Affairs
810 Vermont Ave. NW
Washington, DC 20420

Dear Secretary Wilkie,

We are writing today to encourage you to use your authority as the Secretary of Veterans Affairs to conduct a rigorous clinical trial into the safety and efficacy of medicinal cannabis for veterans with post-traumatic stress disorder (PTSD) and chronic pain so that we can better understand the potential benefits or dangers of medicinal cannabis.

The Department of Veterans Affairs (VA) is already conducting multiple small-scale studies into the potential health benefits of medicinal cannabis, and we believe VA has the authority, ability and capacity to carry out such a study. Many of our nation's veterans already use medicinal cannabis, and they deserve to have full knowledge of the potential benefits and side effects of this alternative therapy.

According to a recent New York Times article published on July 25, veterans in Northern California are lining up to receive free marijuana, often without a doctor's prescription or understanding of any potentially harmful drug interactions. These veterans primarily get their health care from VA, but because of restrictive regulations, VA doctors are barred from recommending and, until recently, discussing, medicinal cannabis. The pervasive lack of research makes their jobs even more difficult, leaving VA clinicians flying blind, without concrete recommendations to provide veterans. VA doctors deserve to be fully informed about medicinal cannabis so that they can provide fact-based guidance to their patients.

Without rigorous, Department-led research into the safety and efficacy of medicinal cannabis for treating veterans with PTSD and chronic pain, both VA doctors and veterans will remain in the dark about this potentially beneficial alternate treatment. In fact, many veterans state that cannabis is better at reducing and controlling their pain than prescription painkillers and opioids. While in the midst of a deadly opioid epidemic, it is irresponsible to turn a blind eye to a possible substitute to harmful opioids. Additionally, one study in New Mexico found that patients using cannabis experienced a 75 percent reduction in their Clinician Administered Posttraumatic Scale score compared to patients not using cannabis to treat their PTSD symptoms.

Many veterans with these invisible wounds are suffering, and the pharmaceuticals prescribed to them are not providing meaningful relief. VA already has the authority to conduct studies into the benefits and side effects of medicinal cannabis, and is in fact already conducting two small-scale studies. We strongly encourage VA to take its cues from veterans, who, according to The American Legion's survey of its membership, overwhelmingly support research into medicinal cannabis.

We, and all of our nation's veterans, look forward to your prompt response.

Sincerely,

Jon Tester
Ranking Member
Senate Committee on Veterans' Affairs

David P. Roe, M.D.
Chairman
House Committee on Veterans' Affairs

Tim Walz
Ranking Member
House Committee on Veterans' Affairs

Dan Sullivan
United States Senator
Senate Committee on Veterans' Affairs

EXHIBIT 7

Congress of the United States
Washington, DC 20515

August 31, 2018

The Honorable Jefferson Sessions
Attorney General
U.S. Department of Justice (DOJ)
950 Pennsylvania Avenue, NW
Washington, DC 20530-0001

Dear Attorney General Sessions:

In light of the fact that August 11, 2018 marked two years since the Drug Enforcement Administration (DEA) stated that they would accept registrations for manufacturers of marijuana for research usage, we write to encourage you to finalize your review of the submitted applications.

As we expressed to you nearly four months ago, in our letter dated April 30, 2018, compliant manufacturers are attempting to provide state and federal governments and medical professionals with rigorous research on cannabis' effects, both adverse and therapeutic, but their applications to do so have not been assessed. Our nation needs scientific research to analyze the medical applications of cannabis so we may determine appropriate federal marijuana policy in accordance with federal law. It is good policy, it is simply the right thing to do, and it falls within our national controlled substances regulatory framework.

As a bipartisan group of Members of Congress, we feel obliged to make clear our position on marijuana research:

1. The production of marijuana for compliant research should be apolitical.

2. Lawmakers, regulators, law enforcement officials and patients must be able to draw from a robust body of scientific research to make informed decisions about marijuana usage.

3. The need for expanded marijuana research in the United States is critical and urgent.

To prevent further delays in approving pending DEA applications for licenses to manufacture marijuana for research purposes, we ask you to respond to the following questions at your earliest convenience:

1. What is the current status of the twenty-six marijuana manufacturer applications?

2. In the past twelve months, excluding Schedule I Bulk Manufacturer registrations for marijuana, how many new DEA registrations has DOJ reviewed?

3. What steps have both the DEA and DOJ taken to review the twenty-six marijuana manufacturer applications currently pending?

4. By what date do you estimate the DEA will have completed its review of the twenty-six marijuana applications and commence registration of new marijuana manufacturers?

We look forward to your department addressing these questions and swiftly registering additional producers of marijuana for research. Thank you for your attention to this matter.

Sincerely,

Carlos Curbelo
Member of Congress

Jimmy Panetta
Member of Congress

Matt Gaetz
Member of Congress

Earl Blumenauer
Member of Congress

Dana Rohrabacher
Member of Congress

Steve Cohen
Member of Congress

Don Young
Member of Congress

Charlie Crist
Member of Congress

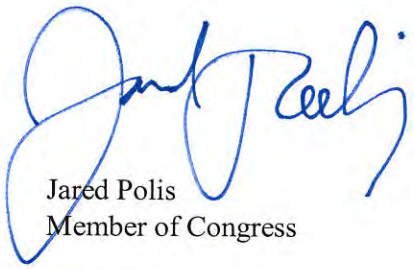
Tom Garrett
Member of Congress

Eleanor Holmes Norton
Member of Congress

Ryan Costello
Member of Congress

Anna G. Eshoo
Member of Congress

Zoe Lofgren
Member of Congress



Jared Polis
Member of Congress

EXHIBIT 8

Congress of the United States
Washington, DC 20515

September 28, 2018

The Honorable Uttam Dhillon
Acting Administrator
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, VA 22152

The Honorable Jeff Sessions
Attorney General
United States Department of Justice
950 Pennsylvania Avenue, NW
Washington, DC 20530

Dear Acting Administrator Dhillon and Attorney General Sessions:

Considering the recent decision by the Drug Enforcement Administration (DEA) to approve the importation from Canada of marijuana for research, we write with deep concern and with questions over the delay in approving additional approved domestic manufacturers of cannabis for this same purpose.

Cannabis offers breakthrough possibilities to help alleviate suffering and disease, but more research is needed. Currently, there is only one legal domestic supplier of marijuana for research purposes. Many have raised concerns about the cannabis it manufactures, however, such as the quality of the product. In August 2016, DEA adopted a new policy so as to increase the number of domestic manufacturers in order to increase the amount of cannabis supply and facilitate research.

Further, on October 18, 2017, you, Attorney General Sessions, testified before the Senate Judiciary Committee. In response to a question from Senator Orrin Hatch about federally-approved manufacturers of research cannabis, you stated "I think it would be healthy to have some more competition in the supply." We agree. Fortunately, over two dozen American companies have filed applications to manufacture cannabis products for research purposes.

Unfortunately, in the two years since DEA's new policy, no additional manufactures have been approved. There have been several unsuccessful attempts to ascertain the cause of this delay, most recently a July 25, 2018 letter from a bipartisan group of Senators and an August 31 letter from a bipartisan group of Representatives.

The need for additional domestic manufacturers of marijuana for research purposes was illustrated a few days ago by DEA. On Tuesday, September 18, it granted approval to the University of California San Diego's *Center for Medical Cannabis Research* to import capsules of THC and CBD from a Canadian company, Tilray Inc., for purposes of medical research. The one manufacturer in the U.S. does not offer capsules of cannabis compounds. If there were other domestic manufacturers, they might offer this option.

On April 18, 2017, President Trump issued an executive order to "Buy American and Hire American." Despite the Department of Justice (DOJ) and DEA possessing over two dozen applications from qualified domestic manufacturers, however, DEA approved the importation of cannabis products from Canada. Adding insult to injury, one application to produce research

cannabis was submitted by a campus within the University of California system — and one campus of that system will be the eventual recipient of Tilray, Inc.'s THC and CBD products.

We should note that just recently the House Judiciary Committee approved by voice vote the *Medical Cannabis Research Act*. This bill would require there be at least three domestic suppliers of cannabis for research purposes. There is strong and bipartisan interest in Congress in increasing the number of manufacturers in the U.S. of cannabis for research. While Congress will act if the Administration does not, the Administration could make this goal a reality much more quickly if it approved some of the pending applications.

With that in mind, and considering the news of the need to import cannabis products from Canada for U.S. research, we would like answers to the following questions, some of which have been asked by some of us previously:

1. What is the current status of the twenty-six cannabis manufacturer applications? How long has each been pending before DOJ and DEA?

2. What steps have the DEA and DOJ taken to review the cannabis manufacturer applications currently pending? What are the reasons these applications have not been approved?

3. When do you estimate the DEA and DOJ will complete their review of all of the cannabis manufacturing applications and begin approving some as new manufacturers?

4. In the past twelve months, excluding Schedule I Bulk Manufacturer registrations for cannabis, how many other DEA registrations has DOJ reviewed?

We look forward to working with the Administration to see that our domestic need for cannabis for research can be met by American institutions. Your prompt response would be greatly appreciated. Thank you for your time and consideration.

Sincerely,

Matt Gaetz
Member of Congress

Eric Swalwell
Member of Congress

Cc: Dr. Nora D. Volkow, Director, National Institute on Drug Abuse

Earl Blumenauer
Member of Congress

Steve Cohen
Member of Congress

Peter DeFazio
Member of Congress

Pramila Jayapal
Member of Congress

Zoe Lofgren
Member of Congress

Seth Moulton
Member of Congress

Eleanor Holmes Norton
Member of Congress

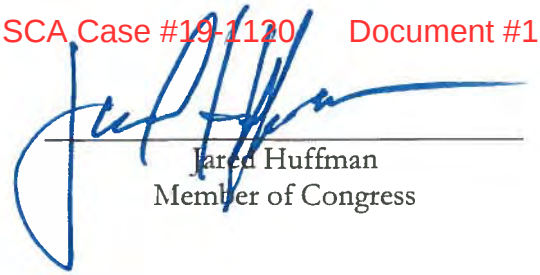
Jimmy Panetta
Member of Congress

Chellie Pingree
Member of Congress

Jared Polis
Member of Congress

Dana Rohrabacher
Member of Congress

Darren Soto
Member of Congress



Jared Huffman
Member of Congress

EXHIBIT 9

United States Senate
WASHINGTON, DC 20510

July 25, 2018

The Honorable Jeff Sessions
Attorney General
U.S. Department of Justice
950 Pennsylvania Avenue, NW
Washington, DC 20530-0001

Dear Attorney General Sessions:

We write to encourage you to finalize your review of applications submitted to the Drug Enforcement Administration (DEA) for licenses to manufacture marijuana for scientific research. Our nation's need for meaningful federally sanctioned research is critical. Research and medical communities should have access to research-grade materials to answer questions around marijuana's efficacy and potential impacts, both positive and adverse. Finalizing the review of applications for marijuana manufacturing will assist in doing just that.

For nearly fifty years, the University of Mississippi has had the sole contract with the National Institute on Drug Abuse (NIDA) to grow cannabis for research purposes. To expand the number of manufacturers, the DEA submitted a notice in the Federal Register on August 11, 2016, soliciting applications for licenses to manufacture marijuana for research purposes. Under this notice, DEA explained its legal authority to "increase the number of entities registered under the Controlled Substances Act (CSA) to grow (manufacture) marijuana to supply legitimate researchers in the United States."[1] However, almost two years have passed since the DEA's notice without any new schedule I marijuana manufacturer registrations.

On April 25, 2018, during testimony before the Senate Appropriations Subcommittee on Commerce, Justice, Science, and Related Agencies, in response to questioning you stated: "We are moving forward and we will add, fairly soon . . . additional suppliers of marijuana under the Controlled [Substances Act]."[2] In a prior hearing, you testified: "It would be healthy to have some more competition in the [marijuana] supply."[3]

Additional registered marijuana manufacturers in the United States will assist not only in expanding legitimate research opportunities, but also will act in a way that allows for the United States' continued compliance with the United Nations' Single Convention on Narcotics Drugs. Specifically, in DEA's August 2016 notice, the agency explained, "DEA believes it would be consistent with the purposes of articles 23 and 28 of the Single Convention for DEA to register

[1] https://www.federalregister.gov/documents/2016/08/12/2016-17955/applications-to-become-registered-under-the-controlled-substances-act-to-manufacture-marijuana-to.
[2] "Attorney General Sessions on Justice Department Budget Request," C-SPAN, 25 April 2018, https://www.c-span.org/video/?444368-1/attorney-general-declines-resign-mueller-rosenstein-fired.
[3] "Justice Department Oversight Hearing," C-SPAN, 18 Oct. 2017, https://www.c-span.org/video/?434413-1/attorney-general-interviewed-special-counsel.

marijuana growers outside of the [National Institute on Drug Abuse]-contract system to supply researchers, provided the growers agree that they may only distribute marijuana with prior, written approval from DEA."

To prevent further delays in approving the at least twenty-six pending DEA applications for licenses to manufacture marijuana for research purposes, we ask you to respond to the following questions and requests by August 10, 2018:

1) What is the currents status of the twenty-six marijuana manufacturer applications?

2) What steps have both DEA and DOJ taken to review the twenty-six marijuana manufacturer applications currently pending?

3) By what date do you estimate the DEA will have completed its review of the twenty-six marijuana applications and commence registration of new marijuana manufacturers?

4) Please share DOJ's analysis of the Single Convention and if the opinion of the Justice Department is the same or similar to that of DEA's.

5) If there are legal barriers to licensing multiple schedule I marijuana manufacturers under the Single Convention, please identify and explain them.

Thank you for your attention to this matter.

Sincerely,

BRIAN SCHATZ
United States Senator

CHUCK GRASSLEY
United States Senator

CORY GARDNER
United States Senator

KIRSTEN GILLIBRAND
United States Senator

AMY KLOBUCHAR
United States Senator

CHRISTOPHER A. COONS
United States Senator

ORRIN HATCH
United States Senator

TIM KAINE
United States Senator

EXHIBIT 10

United States Senate
WASHINGTON, DC 20510

March 28, 2019

The Honorable William Barr
Attorney General
U.S. Department of Justice
950 Pennsylvania Avenue, NW
Washington, DC 20530-0001

Dear Attorney General Barr:

We write to express our opposition to any attempt to reinterpret the United States' obligations under the United Nations' Single Convention on Narcotics of 1961 (Single Convention), which governs the international regulation of controlled substances like marijuana. We have concerns that any changes will unnecessarily hinder the advancement of research on the effects of marijuana for medicinal or therapeutic purposes.

While the Single Convention contained a research exception for the production of controlled substances, the treaty intended to limit the production and distribution of the controlled substances outside of the direct oversight and supervision of the federal government. However, after years of limited research on the effects of medical marijuana, and after many states had moved forward with legalization, the Drug Enforcement Administration (DEA), in consultation with the National Institute on Drug Abuse (NIDA) and the Food and Drug Administration, reassessed their need to provide an adequate supply of research-grade marijuana.

On August 12, 2016, the DEA issued a request for applications to manufacture marijuana for research purposes.[1] In the agency's analysis of the Single Convention, the DEA outlined five conditions for the lawful cultivation of marijuana under Articles 23 and 28 of the treaty. The DEA, as the agency delegated with carrying out the functions of the Single Convention, must:

1. Designate the areas in which, and the plots of land on which, cultivation of the cannabis plant for the purpose of producing cannabis shall be permitted;
2. License cultivators authorized to cultivate cannabis;
3. Specify through such licensing the extent of the land on which the cultivation is permitted;
4. Purchase and take physical possession of all cannabis crops from all cultivators as soon as possible, but not later than four months after the end of the harvest; and
5. Have the exclusive right of importing, exporting, wholesale trading and maintaining stocks of cannabis.

[1] 21 CFR Part 1301, https://www.federalregister.gov/documents/2016/08/12/2016-17955/applications-to-become-registered-under-the-controlled-substances-act-to-manufacture-marijuana-to.

Historically, this operated as a single contract with the National Institute on Drug Abuse (NIDA), through which the federal government was able to maintain a monopoly of the wholesale distribution of the cultivated marijuana. However, to increase the supply of the research-grade marijuana, the DEA revised its oversight and supervisory role. As the agency explained:

> DEA believes it would be consistent with the purposes of articles 23 and 28 of the Single Convention for DEA to register marijuana growers outside of the [National Institute on Drug Abuse]-contract system to supply researchers, provided the growers agree that they may only distribute marijuana with prior, written approval from DEA.

We agree with DEA's analysis that the registration scheme meets the federal government's obligations under the Single Convention. Furthermore, the registration of new manufacturers of research-grade marijuana meets a real need in our country to advance the science behind medical marijuana. No additional changes to our interpretation of the Single Convention are needed to meet this goal.

We believe the licensed production of marijuana for research is critically important. After over two and a half years of delay, it is imperative that you advance the process for registering new manufacturers of research-grade marijuana. We thank you for your consideration of our concerns, and we look forward to the opportunity to work with you this issue.

Sincerely,

BRIAN SCHATZ
United States Senator

CORY A. BOOKER
United States Senator

cc: Uttam Dhillon
Acting Administrator
U.S. Drug Enforcement Administration

EXHIBIT 11

United States Senate
WASHINGTON, DC 20510

April 2, 2019

The Honorable William Barr
Attorney General
U.S. Department of Justice
950 Pennsylvania Avenue, NW
Washington, DC 20530-0001

Dear Attorney General Barr:

We write to follow up on previous inquires about the status of pending applications submitted to the Drug Enforcement Administration (DEA) for licenses to manufacture marijuana for scientific research. These inquiries were made in a previous letter sent to then-Attorney General Jeff Sessions encouraging the Department of Justice to finalize its review of the applications. The Department has not responded to the letter, sent on July 25, 2018. Inquiries were also made by both Senator Chuck Grassley[1] and Ranking Member Dianne Feinstein[2] in questions for the record for your confirmation hearing, to which you responded by committing to review the letter and the status of the pending applications. We are encouraged by your comments, and we look forward to working with the Department on this issue.

Our nation's need for meaningful federally sanctioned research is critical. Research and medical communities should have access to research-grade materials to answer questions around marijuana's efficacy and potential impacts, both positive and adverse. Finalizing the review of applications for marijuana manufacturing will assist in doing just that.

For nearly fifty years, the University of Mississippi has had the sole contract with the National Institute on Drug Abuse to grow cannabis for research purposes. To expand the number of manufacturers, the DEA submitted a notice in the Federal Register on August 11, 2016, soliciting applications for licenses to manufacture marijuana for research purposes. Under this notice, DEA explained its legal authority to "increase the number of entities registered under the Controlled Substances Act (CSA) to grow (manufacture) marijuana to supply legitimate researchers in the United States."[3] However, over two year and a half years have passed since the DEA's initial notice without any new schedule I marijuana manufacturer registrations.

On April 25, 2018, during testimony before the Senate Appropriations Subcommittee on Commerce, Justice, Science, and Related Agencies, in response to questioning, Sessions stated: "We are moving forward and we will add, fairly soon . . . additional suppliers of marijuana under

[1] "Questions for the Record, William P. Barr, Nominee to be United States Attorney General: Questions from Senator Grassley," https://www.judiciary.senate.gov/imo/media/doc/Barr%20Responses%20to%20Grassley%20QFRs1.pdf.
[2] "Questions for the Record, William P. Barr, Nominee to be United States Attorney General: Questions from Senator Feinstein," https://www.judiciary.senate.gov/imo/media/doc/Barr%20Responses%20to%20Feinstein%20QFRs1.pdf.
[3] https://www.federalregister.gov/documents/2016/08/12/2016-17955/applications-to-become-registered-under-the-controlled-substances-act-to-manufacture-marijuana-to.

the Controlled [Substances Act]."[4] In a prior hearing, Sessions testified: "It would be healthy to have some more competition in the [marijuana] supply."[5]

To prevent further delays in approving the pending DEA applications for licenses to manufacture marijuana for research purposes, we ask you to respond to the following questions and requests by April 23, 2019:

1) What is the current status of each marijuana manufacturer application?

2) What steps have both DEA and DOJ taken to review each marijuana manufacturer application currently pending?

3) By what date do you estimate the DEA will have completed its review of all the marijuana manufacturer applications and commence registration of new marijuana manufacturers?

4) Please share DOJ's analysis of the Single Convention and if the opinion of the Justice Department is the same or similar to that of DEA's.

5) If there are legal barriers to licensing multiple schedule I marijuana manufacturers under the Single Convention, please identify and explain them.

6) What impact, if any, did the enactment of the 2018 Farm Bill have on the pending applications? If any of the pending applications were to manufacture hemp-derived CBD for research purposes, does DOJ intend to notify those applicants that a bulk manufacturer registration is no longer needed? If so, when? If not, why not?

In your response to Senator Grassley, you said: "I support the expansions of marijuana for manufacturers for scientific research consistent with law," and in your response to Senator Feinstein, in reference to the pending applications, you said: "If confirmed, I can commit to reviewing the matter." We look forward to working with you on this effort, and we thank you for your attention to this matter.

Sincerely,

BRIAN SCHATZ
United States Senator

DIANNE FEINSTEIN
United States Senator

[4] "Attorney General Sessions on Justice Department Budget Request," C-SPAN, 25 April 2018, https://www.c-span.org/video/?444368-1/attorney-general-declines-resign-mueller-rosenstein-fired.
[5] "Justice Department Oversight Hearing," C-SPAN, 18 Oct. 2017, https://www.c-span.org/video/?434413-1/attorney-general-interviewed-special-counsel.

LISA MURKOWSKI
United States Senator

CORY GARDNER
United States Senator

CHRISTOPHER A. COONS
United States Senator

TIM KAINE
United States Senator

EXHIBIT 12

Congress of the United States
Washington, DC 20515

May 7, 2019

The Honorable William Barr
Attorney General
United States Department of Justice
950 Pennsylvania Avenue, NW
Washington, DC 20530

The Honorable Uttam Dhillon
Acting Administrator
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, VA 22152

Dear Attorney General Barr and Acting Administrator Dhillon:

We write to urge you to do more to speed research on the medicinal benefits of cannabis.

Some of us have written to the Department of Justice (DOJ) and Drug Enforcement Administration (DEA) before on the topic of cannabis, and we write again because the matter is of such importance. There is tremendous evidence that cannabis has the power to treat a variety of medical ailments; that is why 33 states and the District of Columbia have made it legal for that purpose.

In fact, the federal government recognizes the healing properties of cannabis as well. So far the Food and Drug Administration (FDA) has approved one compound produced by the plant and two compounds which are synthetic substances mimicking ones produced by the plant, all known as cannabinoids, for medical use. More research is needed, however, to make additional products available.

Unfortunately, the federal government stands in the way. The application process to research cannabis is one that is arduous and long. First, one who wishes to engage in this research must at the very least work with three separate federal entities – the National Institute on Drug Abuse (NIDA), DEA, and FDA. Approval is required by DEA, which involves a site inspection, and FDA. This is not including any involvement by governments at the state or local level.

Second, there is only one federally-approved grower of cannabis for research in the United States – the University of Mississippi. Researchers must wait to be provided the cannabis to begin their work. Beyond any delays in time this adds, the cannabis itself is generally regarded has having poor quality. The University of Mississippi also does not offer cannabinoids.

It is thus not surprising that those who want to research cannabis are frustrated. Some wait months or even years to have their applications approved. And then they have to deal with raw materials that do not always lend themselves to proper research.

We recognize DEA has taken concrete steps to improve research prospects, but they do not go far enough. Specifically, we applaud DEA for improving its application process for research by putting it entirely online in early 2018. But, as John Hudak, a senior fellow at the Brookings Institution, told *Rolling Stone* in February 2018, that is just a "very small drop in the bucket" in terms of speeding up the process. And, we appreciate that DEA has increased its quota in 2019 for growing

cannabis for research purposes by more than five times, writing in the December 28, 2018 *Federal Register* notice approving the quota that it was due to "increased usage projections for federally approved research projects." But, that does not address any delays in receiving cannabis, its quality, or what is presented as materials for research options.

We urge you then to go beyond these steps and do whatever you can to speed up and improve the research application process. Please let us know what you are considering to change the application process so it moves more quickly and what additional resources from Congress would help in that regard.

One action which would be beneficial is to act on one of the 26 pending applications to grow cannabis for research purposes; these applicants could provide better raw materials for research. Some of us have written with questions about these applications previously; we never received a response. So, we would like to re-ask those questions here:

1. What is the current status of the 26 cannabis manufacturer applications? How long has each been pending before DOJ and DEA?

2. What steps have the DEA and DOJ taken to review the cannabis manufacturer applications currently pending? What are the reasons these applications have not been approved?

3. When do you estimate the DEA and DOJ will complete their review of all of the cannabis manufacturing applications and begin approving some as new manufacturers?

4. In the past 12 months, excluding Schedule I Bulk Manufacturer registrations for cannabis, how many other DEA registrations has DOJ reviewed?

We hope DOJ and DEA share our goal of bringing safe and effective medical treatments to those who are suffering as quickly as possible; we believe cannabis can be part of the solution, but we need more research to make that happen.

Thank you for reviewing our request, and we look forward to a prompt response.

Sincerely,

Eric Swalwell
Member of Congress

Matt Gaetz
Member of Congress

Steve Cohen
Member of Congress

Don Young
Member of Congress

Earl Blumenauer
Member of Congress

David P. Joyce
Member of Congress

Jimmy Panetta
Member of Congress

Zoe Lofgren
Member of Congress

Rodney Davis
Member of Congress

Ruben Gallego
Member of Congress

Tulsi Gabbard
Member of Congress

Jan Schakowsky
Member of Congress

Jesus G. "Chuy" Garcia
Member of Congress

Bobby L. Rush
Member of Congress

Barbara Lee
Member of Congress

Ro Khanna
Member of Congress

Debbie Dingell
Member of Congress

Diana DeGette
Member of Congress

Scott Peters
Member of Congress

J. Luis Correa
Member of Congress

Gilbert Ray Cisneros, Jr.
Member of Congress

Raul M. Grijalva
Member of Congress

Jared Huffman
Member of Congress

Donna E. Shalala
Member of Congress

Seth Moulton
Member of Congress

Eleanor Holmes Norton
Member of Congress

Dina Titus
Member of Congress

Henry C. "Hank" Johnson
Member of Congress

Peter A. DeFazio
Member of Congress

Rashida Tlaib
Member of Congress

Cc: Dr. Nora D. Volkow, Director, National Institute on Drug Abuse

EXHIBIT 13

From: "Roth, Kurtis R." <Kurtis.R.Roth@usdoj.gov>
Date: August 30, 2018 at 9:46:24 AM MST
To: Sue Sisley MD <ssisleymd@gmail.com>
Subject: RE: Signed document ApplicationDEABulkManufacturerAddendum attached

Dr. Sisley,

The status of the application remains unchanged. The DEA and DOJ are discussing applications involving the bulk manufacture of drug code 7360 for research purposes.

Regards,

Kurt Roth
Unit Chief Regulatory Unit (DRGR)
Diversion Regulatory Section
DEA Diversion Control Division
202-307-4022

From: Sue Sisley MD <ssisleymd@gmail.com>
Sent: Thursday, August 30, 2018 12:09 PM
To: Roth, Kurtis R. <KRRoth@DEA.USDOJ.GOV>
Subject: Fwd: Signed document ApplicationDEABulkManufacturerAddendum attached

Sue Sisley, MD
(480) 326-6023

Begin forwarded message:

From: Sue Sisley MD <ssisleymd@gmail.com>
Date: August 30, 2018 at 8:55:28 AM PDT
To: "Brown, Marquita L." <Marquita.L.Brown@usdoj.gov>
Cc: "Earl S. Doubet" <Earl.S.Doubet@usdoj.gov>, Irvin.X.Reaves@usdoj.gov
Subject: Re: Signed document ApplicationDEABulkManufacturerAddendum attached

Re: application control number is H16068002E

It's been two years since the DEA announcement on the federal register about licensing other bulk manufacturers.

I have contacted my local DEA office regularly asking them the status of our application over the past two years and continue to get a vague response saying they have no idea when the application will ever be processed.

Can you provide us another update from the national office on when the applications will be evaluated?

I know we've discussed this on the phone several times over the last few years and I continue to hear from you that you are unsure of when this application above will be assessed. So given the continual uncertainty from your office, I've stopped inquiring with national office because this seemed futile.

But since we now passed the two year anniversary since the announcement August 12, 2016,
I would again like to ask if there is any meaningful progress since the last time we talked.

Do you have a date for when I can expect this application to be adjudicated?

Applications To Become Registered Under the Controlled Substances Act To Manufacture Marijuana To Supply Researchers in the United States

A Rule by the Drug Enforcement Administration on 08/12/2016

PUBLISHED DOCUMENT

Start Printed Page 53846

AGENCY:

Drug Enforcement Administration, Department of Justice.

ACTION:

Policy statement.

SUMMARY:

To facilitate research involving marijuana and its chemical constituents, DEA is adopting a new policy that is designed to increase the number of entities registered under the Controlled Substances Act (CSA) to grow (manufacture)

DOCUMENT DETAILS

Printed version:
PDF

Publication Date:
08/12/2016

Agencies:
Drug Enforcement Administration

Dates:
August 12, 2016.

Effective Date:
08/12/2016

Document Type:
Rule

Document Citation:
81 FR 53846

Page:
53846-53848 (3 pages)

CFR:
21 CFR 1301

AGENCY:

Drug Enforcement Administration, Department of Justice.

ACTION:

Policy statement.

SUMMARY:

To facilitate research involving marijuana and its chemical constituents, DEA is adopting a new policy that is designed to increase the number of entities registered under the Controlled Substances Act (CSA) to grow (manufacture) marijuana to supply legitimate researchers in the United States. This policy statement explains how DEA will evaluate applications for such registration consistent with the CSA and the obligations of the United States under the applicable international drug control treaty.

DATES:

August 12, 2016.

FOR FURTHER INFORMATION CONTACT:

Michael J. Lewis, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598-6812.

SUPPLEMENTARY INFORMATION:

DOCUMENT DETAIL
Printed version:
PDF
Publication Date:
08/12/2016
Agencies:
Drug Enforcemer
Dates:
August 12, 2016
Effective Date:
08/12/2016
Document Type:
Rule
Document Citatio
81 FR 53846
Page:
53846-53848 (3
CFR:
21 CFR 1301
Agency/Docket N
Docket No. DEA-
Document Numb
2016-17955
DO
ENHANCED CONTE
regulations.g
Docket Number:
DEA-2016-0013
ENH

You can see that the last communication I had from you guys was July 2017 simply to update the drug code on the application.
No further information about the timeline for moving forward.

Sue Sisley, MD
(480) 326-6023

On Jul 31, 2017, at 9:09 AM, Sue Sisley MD <ssisleymd@gmail.com> wrote:

Hi Marquita

Are you asking why I sent that to you?

Mr Doubet asked me to edit the application to reflect that indeed drug code 7370 was also being addressed by all of the answers in the supplemental questionnaire.

Sue Sisley, MD
(480) 326-6023

On Jul 31, 2017, at 7:41 AM, Brown, Marquita L. <Marquita.L.Brown@usdoj.gov> wrote:

Yes I can. Why what's up

From: Sue Sisley MD [mailto:ssisleymd@gmail.com]
Sent: Saturday, July 29, 2017 2:46 PM
To: Brown, Marquita L.; Doubet, Earl S.
Subject: Signed document ApplicationDEABulkManufacturerAddendum attached

Marquita, can you confirm that you can open this?
And then can you let me know if this will be sufficient?

EXHIBIT 14

MAPS Public Benefit Corporation

Purpose

This document records the secondary testing performed on cannabis provided by the National Institute on Drug Abuse (NIDA) to the MJP-1 protocol investigating four difference kinds of marijuana in 76 veterans suffering from chronic, treatment-resistant posttraumatic stress disorder (PTSD). The study is sponsored by the Multidisciplinary Association for Psychedelic Studies (MAPS) and is funded by the Colorado Department of Public Health (CDPHE). This document will detail the testing performed and justification for using NIDA-supplied cannabis for the MJP-1 clinical trial.

Secondary Cannabis Testing Procedures

MAPS intended to test NIDA cannabis to verify the chemical composition of each concentration of cannabis after receipt as detailed in the study protocol. Prior to receipt at Scottsdale Research Institute (SRI), an MJP-1 clinical site, MAPS had been informed that NIDA cannabis from another batch, stored at refrigerated temperatures at another clinical site (not related to MAPS or the MJP-1 study) had become visibly moldy after two weeks of storage at refrigerated temperatures. The MJP-1 study had originally planned to store packaged cannabis at refrigerated temperatures prior to subject dispensation. Due to this finding, MAPS conducted further testing of Total Yeast and Mold (TYM), dangerous microbes, pesticides and heavy metals to determine the appropriate storage conditions.

Cannabis grown by NIDA contractors was received from Research Triangle International (RTI) at SRI on 25 August 2016. Product was immediately weighed using clean laboratory techniques and stored in the -20ºC freezer. Two Schedule I-licensed analytical laboratories were used to test samples of cannabis. Potency and TYM were tested at Industrial Laboratories in Colorado. TYM, heavy metals (arsenic, cadmium, lead, and mercury), E. coli/coliforms, Salmonella, Gram-negative bacteria, aflatoxins B1, B2, G1, G2, and ochratoxin A, aerobic microbes, pesticides and terpenes were tested at the University of Illinois at Chicago (UIC). Schedule I licenses were reviewed for each laboratory. DEA-222 forms were used to ensure chain of custody for each shipment of cannabis sent to the laboratories.

Release specifications for the cannabis, such as pass/fail or upper limits guidance for impurities, have not been provided by NIDA nor the Food and Drug Administration (FDA). The sponsor assumes this information is kept within the FDA Drug Master File (DMF) that NIDA opened. Despite being a publicly-funded agency, NIDA considers its DMF proprietary information for manufacturers and is not willing to let MAPS or any other researchers using NIDA marijuana review the contents. MAPS seeks release specifications, test results, and documentation from NIDA that further provides characterization of the NIDA supplied product.

After reviewing and analyzing results of secondary testing, the MAPS clinical group met with Investigators as well as Medical Monitors and decided to move forward with the MJP-1 clinical trial with the only product available, NIDA-supplied product. The sponsor has determined the product will not be kept under refrigerated storage based on concerns about mold but will be frozen until distribution to participants and then kept at room temperature by participants. Rationale for this decision is provided within this report. A table of all testing results and dates of testing for the above tests can be found in the following section.

Summary of Findings

Table 1: Key to Test Article, Batch # and Potency

Test Article	Type	Batch #	Potency RTI
1	Low THC/High CBD	13784-1114-18-5	THC 0.53 ± 0.02%/CBD 10.9 ± 1.14%
2	High THC/Low CBD	13784-1107-22	THC 12.3± 1.37%/CBD 0.03 ± 0.01%
3	THC/CBD	13851-0715-139	THC 7.9 ± 0.41%/CBD 8.1 ± 0.56%
4	Low THC/High CBD	13786-1214-26	THC 0.50 ± 0.03%/CBD 11.4 ± 0.68%
5	Placebo	13322-21-3	THC 0.010%/CBD ND
6	Placebo	9022-0598-111-1	THC 0.026%/CBD 0.002%

Potency: Of the six batches tested, only one batch differed significantly from the potency information provided by NIDA. The High THC/Low CBD blend (batch 13784-1107-22) provided from NIDA has shown varying levels of THC potency throughout the testing process, as shown in Table 2. Testing of THC upon arrival at Research Triangle International (RTI) from University of Mississippi was 13.17%. Testing of THC at RTI has varied from 12.6% (Jun/Jul 2015), 10.6% (Dec 2015), 12.3% (Jul 2016) and 13.0% (Nov 2016). Secondary testing at Industrial Laboratories showed THC results of 7.89% (Sep 2016) and 8.07% (Oct 2016).

MAPS explored with NIDA the potential availability of another batch of High THC available in the quantity that would meet the needs of the clinical trial. NIDA informed MAPS that the only other batch they would have that would meet study supply and quantity would have a THC content of around 9%. MAPS decided to use the current batch of High THC/Low CBD (13784-1107-22) as subjects will self-titrate and the amount of cannabis smoked will be collected throughout the study. Clinical results will be reported indicating a range of observed potencies (THC 7.89%-13.17%) for the High THC/Low CBD blend.

Table 2: NIDA Potency Testing Comparison

		University of Mississippi		RTI								Industrial Laboratories			
Test Article	Type	(% Δ^9-THC) upon Receipt	(% CBD) upon Receipt	(% Δ^9-THC) Jun 2015	(% CBD) Jun 2015	(% Δ^9-THC) Dec 2015	(% CBD) Dec 2015	(% Δ^9-THC) Jul 2016	(% CBD) Jul 2016	(% Δ^9-THC) Nov 2016	(% CBD) Nov 2016	(% Δ^9-THC) Sep 2016	(% CBD) Sep 2016	(% Δ^9-THC) Oct 2016	(% CBD) Oct 2016
1	Low THC/High CBD	0.52	13.96	0.47	11.4	0.46	12.7	0.53	10.9	0.58	13.8	0.42	10.76		
2	High THC/Low CBD	13.17	0.05	12.6	0.04	10.6	0.03	12.3	0.03	13.0	0.08	7.89	<LOQ	8.07	0.05
3[1]	THC/CBD			7.7	7.9	8.9	9.3	7.9	8.1	10.8	11.1	7.31	8.43		
4[2]	Low THC/High CBD	0.42	11.13			0.16	11.53	0.50	11.4	0.49	13.2	0.35	10.89		

[1] Blended material (1378A and 1304-1)
Original potencies (UMiss) before blending: barrel 1378A - THC/CBD: 9.13/15.49 barrel 13401-1 - THC/CBD: 13.17/0.05
[2] Received in December 2015

Total Yeast and Mold*:* Both placebo batches tested very low in TYM at every testing time point. The four active batches showed varying levels of TYM at each testing time point. All samples were tested directly from frozen storage and after two days, two weeks and three weeks at refrigerated temperatures on 3M Petrifilm plates at Industrial Laboratories. All active samples tested after refrigerated and frozen storage showed elevated mold levels at Industrial Laboratories when tested on 3M Petrifilm plates. TYM testing was performed again at UIC directly from frozen storage at two separate time points using two different plating methods (Neofilm and 3M Petrifilm Plates). The first TYM testing on Neofilm plates showed low levels of mold. As this did not parallel TYM testing at Industrial Laboratories, TYM testing was performed again at UIC on both Neofilm and 3M Petrifilm plates. The 3M plates showed a range of 23,000-44,000 CFU/g and the Neofilm plates showed a range of 38,000-64,000 CFU/g in the second round of TYM testing at UIC. Tables 3 and 4 on the next page show all TYM results. NIDA noted though they do not currently have specification for levels of TYM in their cannabis product, they believe these levels are within acceptable range for orally consumed botanicals. Based on these results and observations from other teams that refrigeration can lead to mold the sponsor has determined the Cannabis will be stored at frozen temperatures of -20ºC up until just prior to dispensation.

Though many legal medical marijuana states have set varying acceptable levels of TYM, there is no agreement on if TYM should be a required test and there are no release specifications or guidelines in place from NIDA or FDA. Using the NIDA-provided Microbiology Safety Testing of Cannabis Whitepaper as a guide, reviewing test results that showed no harmful microbes, and after consulting with plant experts, the MAPS clinical team concluded that the cannabis is safe for use in this clinical trial. Only physically healthy participants who are not immunocompromised will be enrolled. The protocol will exclude any participant that may have an allergy or a past adverse reaction to marijuana. Potential participants will demonstrate immune system health via routine clinical laboratory testing prior to participation. Each lab result will be reviewed by a physician on the study. If a potential participant presents with abnormal white blood cell counts outside of the normal reference range, the study Medical Monitor will be consulted prior to the inclusion of the subject in the clinical trial. Risk is further limited through the daily limit of smoking no more than 1.8 grams per day for only 21 days per batch, with participants randomized to two different batches during the treatment period.

Cannabis will be stored at frozen temperatures of -20ºC up until just prior to dispensation with storage at room temperature after dispensation. Cannabis dispensation procedures were tested with sample product to ensure that mold would not grow under the revised methodology. To ensure a stable product at room temperature, SRI performed visual mold inspection of the cannabis to test for visible mold growth. Frozen cannabis was placed into the ointment jars that will be used for packaging in the clinical trial. The cannabis and jars were left open for a duration to allow evaporation of any excess moisture that could accumulate due to freezing. The jars were labeled Day One through Day Seven, the tops were screwed on and stored at room temperature. Each day staff opened that day's jar, visually inspected it, took photographs and documented their findings (See Attachment A). On each day the product appeared dry and dehydrated. The color of the product was consistent among days and was documented as yellow, brown, and green in color. No mold was observed on any day. A summary with photographs is in Attachment A.

Revised cannabis dispensation procedures will provide participants with a new supply each week from frozen storage, which will ensure fresh supply with limited likelihood of yeast and mold growth. Participants will be directed to store their study drug in locked boxes at room temperature.

Table 3: Industrial Laboratories: 3M Petrifilm Plate – Total Yeast and Mold Refrigerated and Frozen Testing

Test Article	Type	Mold Secondary Testing Baseline 22 Sep 2016 Refrigerated two days prior to testing	Mold Secondary Testing Two weeks 06 Oct 2016 Refrigerated two weeks	Mold Secondary Testing Three weeks 20 Oct 2016 Refrigerated three weeks	Mold Secondary Testing Directly from 20 Oct 2016 Frozen Storage
1	Low THC/High CBD	110,000 CFU/g	170,000 CFU/g	340,000 CFU/g	58,000 CFU/g
2	High THC/Low CBD	70,000 CFU/g	90,000 CFU/g	24,000 CFU/g	64,000 CFU/g
3	THC/CBD	43,000 CFU/g	90,000 CFU/g	43,000 CFU/g	39,000 CFU/g
4	Low THC/High CBD	42,000 CFU/g	120,000 CFU/g	53,000 CFU/g	37,000 CFU/g
5	Placebo	50 CFU/g	70 CFU/g	<50 CFU/g	<50 CFU/g
6	Placebo	60 CFU/g	30 CFU/g	<50 CFU/g	Not performed

Table 4: University of Illinois at Chicago: 3M Petrifilm and Neofilm Plate – Total Yeast and Mold Frozen Testing

Test Article	Type	Neofilm Directly from Frozen Storage 21 Nov 2016	3m Petrifilm Directly from Frozen Storage 02 Dec 2016	Neofilm Directly from Frozen Storage 02 Dec 2016
1	Low THC/High CBD	Positive Lab calculated 16,400	39,000 CFU/g	43,000 CFU/g
2	High THC/Low CBD	Negative* 25= ~10,000 CFU/g Tested at approximately 4	44,000 CFU/g	64,000 CFU/g
3	THC/CBD	Negative* 25= ~10,000 CFU/g Tested at approximately 18-19	23,000 CFU/g	38,000 CFU/g
4	Low THC/High CBD	Negative* 25= ~10,000 CFU/g Tested at approximately 15	30,000 CFU/g	51,000 CFU/g
5	Placebo	Negative*		
6	Placebo	Negative*		

***Negative= below 10,000 CFU/g**

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Microbe testing: All six batches were tested for harmful microbes at UIC. All batches tested negative for harmful microbes.

Mold Related Toxins: All six batches were tested for harmful toxins at UIC. All batches tested negative for harmful toxins.

Pesticide testing: All six batches were tested for pesticides at UIC. All batches tested negative for pesticides.

Table 5: University of Illinois at Chicago: Microbes, Mold Related Toxins, and Pesticide Testing

Test Article	Type	Microbe (E. coli/coliforms, Salmonella, Gram-negative bacteria, aerobic microbes), Aflatoxins B1, B2, G1, G2, and Ochratoxin A and Pesticide Testing
1	Low THC/High CBD	Pesticide: Negative Microbes: Negative
2	High THC/Low CBD	Pesticide: Negative Microbes: Negative
3	THC/CBD	Pesticide: Negative Microbes: Negative
4	Low THC/High CBD	Pesticide: Negative Microbes: Negative
5	Placebo	Pesticide: Negative Microbes: Negative
6	Placebo	Pesticide: Negative Microbes: Negative

MAPS Public Benefit Corporation

Heavy Metal testing: All six batches were tested for heavy metals. All batches tested negative for arsenic, cadmium and mercury. Both placebo batches tested negative for lead. Three active batches tested positive for low levels of lead ranging from 0.86-1.7 mg/kg. One batch tested at 15 mg/kg. This same batch was retested for lead and results showed 0.70 mg/kg and then 0.69 mg/kg upon a third test**.**

All active batches of NIDA cannabis have tested positive for lead (see Table 6). Though many legal medical marijuana states have varying acceptable levels of lead, there are no release specifications or guidelines in place from NIDA nor FDA. The World Health Organization (WHO) Guidelines for assessing quality of herbal medicines with reference to contaminants and residue suggest an upper limit for lead of 10 mg/kg. Only one batch tested higher than this (15 mg/kg), and it was retested within these limits (0.70 mg/kg). The International Programme on Chemical Safety reports, "The Lead was previously evaluated at the sixteenth meeting of the Joint FAO/WHO Expert Committee on Food Additives (Annex 1, reference 30). The Committee established a provisional tolerable weekly intake of 3 mg of lead/person, equivalent to 0.05 mg/kg body weight for adults." Cannabis will be restricted to allow use of up to 1.8 grams per day for each of two 21-day period of administration with two-week cessation between the two administration periods. The amount of possible lead exposure from NIDA cannabis is well within the guidelines available, and thus is safe for use in this clinical trial.

Table 6: University of Illinois at Chicago: Heavy Metal Testing

Test Article	Type	Heavy Metals 02 Dec 2016 ND= Not Detected		Lead retesting 27 Dec 2016	Lead retesting 13 Jan 2017
1	Low THC/High CBD	Arsenic	ND		
		Cadmium	ND		
		Lead	0.93 mg/kg		
		Mercury	ND		
2	High THC/Low CBD	Arsenic	ND		
		Cadmium	ND		
		Lead	15 mg/kg	0.70 mg/kg	0.69 mg/kg
		Mercury	ND		
3	THC/CBD	Arsenic	ND		
		Cadmium	ND		
		Lead	0.86 mg/kg		
		Mercury	ND		
4	Low THC/High CBD	Arsenic	ND		
		Cadmium	ND		
		Lead	1.7 mg/kg		
		Mercury	ND		
5	Placebo	Arsenic	ND		
		Cadmium	ND		
		Lead	ND		
		Mercury	ND		
6	Placebo	Arsenic	ND		
		Cadmium	ND		
		Lead	ND		
		Mercury	ND		

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Attachment A

Day One:

Visible Mold- None
Color- Yellow, brown and green
Texture- Crunchy
Smell- Musty
Other- Twigs and sticks, lose powder

Day Two:

Visible Mold- None
Color- Yellow, brown, dark brown and green
Texture- Dry
Smell- Musty
Other- Twigs and leaves

MAPS Public Benefit Corporation

Day Three:

Visible Mold- None
Color- Yellow, brown, dark brown and green
Texture- Dry
Smell- Musty
Other- Twigs

Day Four:

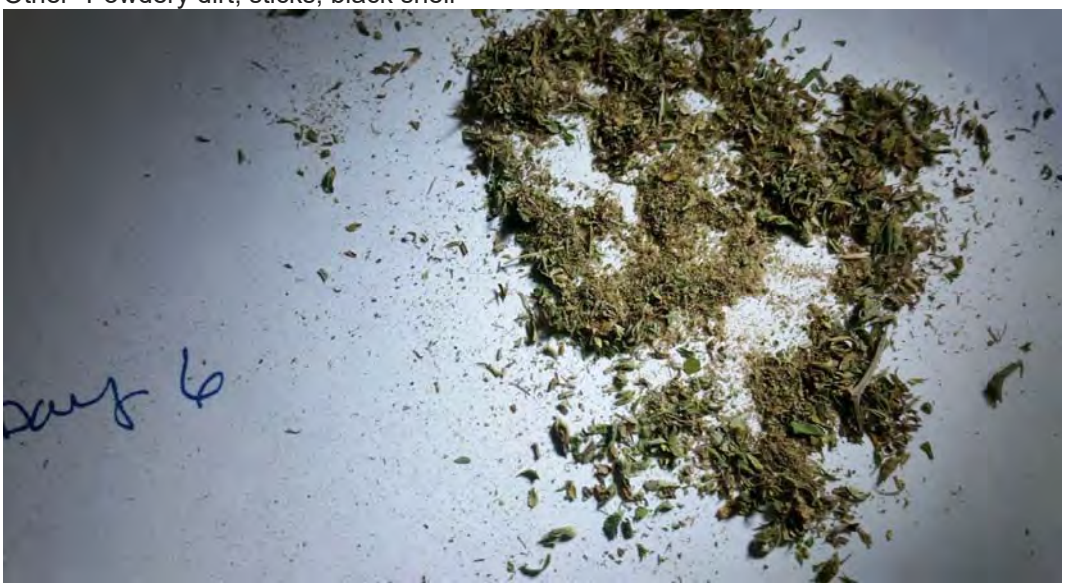
Visible Mold- None
Color- Yellow, brown, dark brown and green
Texture- Crunchy
Smell- Musty
Other- Sticks, powdery substance

Day Five:

Visible Mold- None
Color- Yellow, brown, dark brown and green
Texture- Crunchy
Smell- Musty
Other- Powdery dirt substance, sticks

Day Six:

Visible Mold- None
Color- Yellow, brown, dark brown and green (slightly greener)
Texture- Dry
Smell- Musty, stronger cannabis smell
Other- Powdery dirt, sticks, black shell



MAPS Public Benefit Corporation

Day Seven:

Visible Mold- None
Color- Yellow, brown, dark brown and green
Texture- Crunchy
Smell- Musty
Other- Powdery substance, sticks

EXHIBIT 15

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Chapter II

[Docket No. DEA–426]

Denial of Petition To Initiate Proceedings To Reschedule Marijuana

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Denial of petition to initiate proceedings to reschedule marijuana.

SUMMARY: By letter dated July 19, 2016 the Drug Enforcement Administration (DEA) denied a petition to initiate rulemaking proceedings to reschedule marijuana. Because the DEA believes that this matter is of particular interest to members of the public, the agency is publishing below the letter sent to the petitioner which denied the petition, along with the supporting documentation that was attached to the letter.

DATES: August 12, 2016.

FOR FURTHER INFORMATION CONTACT: Michael J. Lewis, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812.

SUPPLEMENTARY INFORMATION:

July 19, 2016

Dear Ms. Raimondo and Mr. Inslee:

On November 30, 2011, your predecessors, The Honorable Lincoln D. Chafee and The Honorable Christine O. Gregoire, petitioned the Drug Enforcement Administration (DEA) to initiate rulemaking proceedings under the rescheduling provisions of the Controlled Substances Act (CSA). Specifically, your predecessors petitioned the DEA to have marijuana and ''related items'' removed from Schedule I of the CSA and rescheduled as medical cannabis in Schedule II.

Your predecessors requested that the DEA remove marijuana and related items from Schedule I based on their assertion that:

(1) Cannabis has accepted medical use in the United States;

(2) Cannabis is safe for use under medical supervision;

(3) Cannabis for medical purposes has a relatively low potential for abuse, especially in comparison with other Schedule II drugs.

In accordance with the CSA rescheduling provisions, after gathering the necessary data, the DEA requested a scientific and medical evaluation and scheduling recommendation from the Department of Health and Human Services (HHS). The HHS concluded that marijuana has a high potential for abuse, has no accepted medical use in the United States, and lacks an acceptable level of safety for use even under medical supervision. Therefore, the HHS recommended that marijuana remain in Schedule I. The scientific and medical evaluation and scheduling recommendation that the HHS submitted to the DEA is enclosed with this letter.

Based on the HHS evaluation and all other relevant data, the DEA has concluded that there is no substantial evidence that marijuana should be removed from Schedule I. A document prepared by the DEA addressing these materials in detail also is enclosed. In short, marijuana continues to meet the criteria for Schedule I control under the CSA because:

(1) *Marijuana has a high potential for abuse.* The HHS evaluation and the additional data gathered by the DEA show that marijuana has a high potential for abuse.

(2) *Marijuana has no currently accepted medical use in treatment in the United States.* Based on the established five-part test for making such determination, marijuana has no ''currently accepted medical use'' because: As detailed in the HHS evaluation, the drug's chemistry is not known and reproducible; there are no adequate safety studies; there are no adequate and well-controlled studies proving efficacy; the drug is not accepted by qualified experts; and the scientific evidence is not widely available.

(3) *Marijuana lacks accepted safety for use under medical supervision.* At present, there are no marijuana products approved by the U.S. Food and Drug Administration (FDA), nor is marijuana under a New Drug Application (NDA) evaluation at the FDA for any indication. The HHS evaluation states that marijuana does not have a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions. At this time, the known risks of marijuana use have not been shown to be outweighed by specific benefits in well-controlled clinical trials that scientifically evaluate safety and efficacy.

The statutory mandate of Title 21 United States Code, Section 812(b) (21 U.S.C. 812(b)) is dispositive. Congress established only one schedule, Schedule I, for drugs of abuse with ''no currently accepted medical use in treatment in the United States'' and ''lack of accepted safety for use . . . under medical supervision.'' 21 U.S.C. 812(b).

Although the HHS evaluation and all other relevant data lead to the conclusion that marijuana must remain in schedule I, it should also be noted that, in view of United States obligations under international drug control treaties, marijuana cannot be placed in a schedule less restrictive than schedule II. This is explained in detail in accompanying document titled ''Preliminary Note Regarding Treaty Considerations.''

Accordingly, and as set forth in detail in the accompanying HHS and DEA documents, there is no statutory basis under the CSA for the DEA to grant your predecessors' petition to initiate rulemaking proceedings to reschedule marijuana. The petition is, therefore, hereby denied.

Sincerely,

Chuck Rosenberg,

Acting Administrator.

Attachments:

Preliminary Note Regarding Treaty Considerations

Cover Letter from HHS to DEA Summarizing the Scientific and Medical Evaluation and Scheduling Recommendation for Marijuana.

U.S. Department of Health and Human Services (HHS)—Basis for the Recommendation for Maintaining Marijuana in Schedule I of the Controlled Substances Act

U.S. Department of Justice—Drug Enforcement Administration (DEA), Schedule of Controlled Substances: Maintaining Marijuana in Schedule I of the Controlled Substances Act, Background, Data, and Analysis: Eight Factors Determinative of Control and Findings Pursuant to 21 U.S.C. 812(b)

Dated: July 19, 2016.

Chuck Rosenberg,

Acting Administrator, Preliminary Note Regarding Treaty Considerations.

As the Controlled Substances Act (CSA) recognizes, the United States is a party to the Single Convention on Narcotic Drugs, 1961 (referred to here as the Single Convention or the treaty). 21 U.S.C. 801(7). Parties to the Single Convention are obligated to maintain various control provisions related to the drugs that are covered by the treaty. Many of the provisions of the CSA were enacted by Congress for the specific purpose of ensuring U.S. compliance with the treaty. Among these is a scheduling provision, 21 U.S.C. 811(d)(1). Section 811(d)(1) provides that, where a drug is subject to control under the Single Convention, the DEA Administrator (by delegation from the Attorney General) must ''issue an order controlling such drug under the schedule he deems most appropriate to carry out such [treaty] obligations, without regard to the findings required by [21 U.S.C. 811(a) or 812(b)] and without regard to the procedures prescribed by [21 U.S.C. 811(a) and (b)].''

Marijuana is a drug listed in the Single Convention. The Single Convention uses the term ''cannabis'' to refer to marijuana.[1] Thus, the DEA

[1] Under the Single Convention, ''cannabis plant' means any plant of the genus *Cannabis.*'' Article 1(c). The Single Convention defines ''cannabis'' to include ''the flowering or fruiting tops of the cannabis plant (excluding the seeds and leaves when not accompanied by the tops) from which the resin has not been extracted, by whatever name they may be designated.'' Article 1(b). This definition of ''cannabis'' under the Single Convention is slightly less inclusive than the CSA definition of ''marihuana,'' which includes all parts of the cannabis plant except for the mature stalks, sterilized seeds, oil from the seeds, and certain derivatives thereof. *See* 21 U.S.C. 802(16). Cannabis and cannabis resin are included in the list of drugs in Schedule I and Schedule IV of the Single Convention. In contrast to the CSA, the drugs listed in Schedule IV of the Single Convention are also

Administrator is obligated under section 811(d) to control marijuana in the schedule that he deems most appropriate to carry out the U.S. obligations under the Single Convention. It has been established in prior marijuana rescheduling proceedings that placement of marijuana in either schedule I or schedule II of the CSA is ''necessary as well as sufficient to satisfy our international obligations'' under the Single Convention. *NORML* v. *DEA,* 559 F.2d 735, 751 (D.C. Cir. 1977). As the United States Court of Appeals for the DC Circuit has stated, ''several requirements imposed by the Single Convention would not be met if cannabis and cannabis resin were placed in CSA schedule III, IV, or V.'' [2] *Id.* Therefore, in accordance with section 811(d)(1), DEA must place marijuana in either schedule I or schedule II.

Because schedules I and II are the only possible schedules in which marijuana may be placed, for purposes of evaluating this scheduling petition, it is essential to understand the differences between the criteria for placement of a substance in schedule I and those for placement in schedule II. These criteria are set forth in 21 U.S.C. 812(b)(1) and (b)(2), respectively. As indicated therein, substances in both schedule I and schedule II share the characteristic of ''a high potential for abuse.'' Where the distinction lies is that schedule I drugs have ''no currently accepted medical use in treatment in the United States'' and ''a lack of accepted safety for use of the drug . . . under medical supervision,'' while schedule II drugs do have ''a currently accepted medical use in treatment in the United States.'' [3]

Accordingly, in view of section 811(d)(1), this scheduling petition turns on whether marijuana has a currently accepted medical use in treatment in the United States. If it does not, DEA must, pursuant to section 811(d), deny the petition and keep marijuana in schedule I.

As indicated, where section 811(d)(1) applies to a drug that is the subject of a rescheduling petition, the DEA Administrator must issue an order controlling the drug under the schedule he deems most appropriate to carry out United States obligations under the Single Convention, without regard to the findings required by sections 811(a) or 812(b) and without regard to the procedures prescribed by sections 811(a) and (b). Thus, since the only determinative issue in evaluating the present scheduling petition is whether marijuana has a currently accepted medical use in treatment in the United States, DEA need not consider the findings of sections 811(a) or 812(b) that have no bearing on that determination, and DEA likewise need not follow the procedures prescribed by sections 811(a) and (b) with respect to such irrelevant findings. Specifically, DEA need not evaluate the relative abuse potential of marijuana or the relative extent to which abuse of marijuana may lead to physical or psychological dependence.

As explained below, the medical and scientific evaluation and scheduling recommendation issued by the Secretary of Health and Human Services concludes that marijuana has no currently accepted medical use in treatment in the United States, and the DEA Administrator likewise so concludes. For the reasons just indicated, no further analysis beyond this consideration is required. Nonetheless, because of the widespread public interest in understanding all the facts relating to the harms associated with marijuana, DEA is publishing here the entire medical and scientific analysis and scheduling evaluation issued by the Secretary, as well as DEA's additional analysis.

Department of Health and Human Services, Office of the Secretary Assistant Secretary for Health, Office of Public Health and Science, Washington, DC 20201.

June 25, 2015.

The Honorable Chuck Rosenberg

Acting Administrator, Drug Enforcement Administration, U.S. Department of Justice, 8701 Morrissette Drive, Springfield, VA 22152.

Dear Mr. Rosenberg:

Pursuant to the Controlled Substances Act (CSA, 21 U.S.C. § 811(b), (c), and (f)), the Department of Health and Human Services (HHS) is recommending that marijuana continue to be maintained in Schedule I of the CSA.

The Food and Drug Administration (FDA) has considered the abuse potential and dependence-producing characteristics of marijuana.

Marijuana meets the three criteria for placing a substance in Schedule I of the CSA under 21 U.S.C. 812(b)(1). As discussed in the enclosed analyses, marijuana has a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. Accordingly, HHS recommends that marijuana be maintained in Schedule I of the CSA. Enclosed are two documents prepared by FDA's Controlled Substance Staff (in response to petitions filed in 2009 by Mr. Bryan Krumm and in 2011 by Governors Lincoln D. Chafee and Christine O. Gregoire) that form the basis for the recommendation. Pursuant to the requests in the petitions, FDA broadly evaluated marijuana, and did not focus its evaluation on particular strains of marijuana or components or derivatives of marijuana.

FDA's Center for Drug Evaluation and Research's current review of the available evidence and the published clinical studies on marijuana demonstrated that since our 2006 scientific and medical evaluation and scheduling recommendation responding to a previous DEA petition, research with marijuana has progressed. However, the available evidence is not sufficient to determine that marijuana has an accepted medical use. Therefore, more research is needed into marijuana's effects, including potential medical uses for marijuana and its derivatives. Based on the current review, we identified several methodological challenges in the marijuana studies published in the literature. We recommend they be addressed in future clinical studies with marijuana to ensure that valid scientific data are generated in studies evaluating marijuana's safety and efficacy for therapeutic use. For example, we recommend that studies need to focus on consistent administration and reproducible dosing of marijuana, potentially through the use of administration methods other than smoking. A summary of our review of the published literature on the clinical uses of marijuana, including recommendations for future studies, is attached to this document.

FDA and the National Institutes of Health's National Institute on Drug Abuse (NIDA) also believe that work continues to be needed to ensure support by the federal government for the efficient conduct of clinical research using marijuana. Concerns have been raised about whether the existing federal regulatory system is flexible enough to respond to increased interest in research into the potential therapeutic uses of marijuana and marijuana-derived drugs. HHS welcomes an opportunity to continue to explore these concerns with DEA.

Should you have any questions regarding theses recommendations, please contact Corinne P. Moody, Science Policy Analyst, Controlled Substances Staff, Center for Drug Evaluation and Research, FDA, at (301) 796–3152.

Sincerely yours,

Karen B. DeSalvo, MD, MPH, MSc

Acting Assistant Secretary for Health.

Enclosure: Basis for the Recommendation for Maintaining Marijuana in Schedule I of the Controlled Substances Act

listed in Schedule I of the Single Convention and are subject to the same controls as Schedule I drugs as well as additional controls. Article 2, par. 5

[2] The Court further stated: ''For example, [article 31 paragraph 4 of the Single Convention] requires import and export permits that would not be obtained if the substances were placed in CSA schedules III through V. In addition, the quota and [recordkeeping] requirements of Articles 19 through 21 of the Single Convention would be satisfied only by placing the substances in CSA schedule I or II.'' *Id.* n. 71 (internal citations omitted).

[3] As DEA has stated in evaluating prior marijuana rescheduling petitions, ''Congress established only one schedule, schedule I, for drugs of abuse with 'no currently accepted medical use in treatment in the United States'and 'lack of accepted safety for use . . . under medical supervision.' 21 U.S.C. 812(b).'' 76 FR 40552 (2011); 66 FR 20038 (2001).

Basis for the Recommendation for Maintaining Marijuana in Schedule I of the Controlled Substances Act

On November 30, 2011, Governors Lincoln D. Chafee of Rhode Island and Christine O. Gregoire of Washington submitted a petition to the Drug Enforcement Administration (DEA) requesting that proceeding be initiated to repeal the rules and regulations that place marijuana [4] in Schedule I of the Controlled Substances Act (CSA). The petition contends that cannabis has an accepted medical use in the United States, is safe for use under medical supervision, and has a relatively low abuse potential compared to other Schedule II drugs. The petition requests that marijuana and ''related items'' be rescheduled in Schedule II of the CSA. In June 2013, the DEA Administrator requested that the U.S. Department of Health and Human Services (HHS) provide a scientific and medical evaluation of the available information and a scheduling recommendation for marijuana, in accordance with the provisions of 21 U.S.C. 811(b).

In accordance with 21 U.S.C. 811(b), DEA has gathered information related to the control of marijuana (*Cannabis sativa*) [5] under the CSA. Pursuant to 21 U.S.C. 811(b), the Secretary of HHS is required to consider in a scientific and medical evaluation eight factors determinative of control under the CSA. Following consideration of the eight factors, if it is appropriate, the Secretary must make three findings to recommend scheduling a substance in the CSA. The findings relate to a substance's abuse potential, legitimate medical use, and safety or dependence liability.

Administrative responsibilities for evaluating a substance for control under the CSA are performed by the Food and Drug Administration (FDA), with the concurrence of the National Institute on Drug Abuse (NIDA), as described in the Memorandum of Understanding (MOU) of March 8, 1985 (50 FR 9518–20).

In this document, FDA recommends the continued control of marijuana in Schedule I of the CSA. Pursuant to 21 U.S.C. 811(c), the eight factors pertaining to the scheduling of marijuana are considered below.

1. Its Actual or Relative Potential for Abuse

Under the first factor the Secretary must consider marijuana's actual or relative potential for abuse. The CSA does not define the term ''abuse.'' However, the CSA's legislative history suggests the following in determining whether a particular drug or substance has a potential for abuse: [6]

a. There is evidence that individuals are taking the drug or drugs containing such a substance in amounts sufficient to create a hazard to their health or to the safety of other individuals or to the community.

b. There is a significant diversion of the drug or drugs containing such a substance from legitimate drug channels.

c. Individuals are taking the drug or drugs containing such a substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such drugs in the course of his professional practice.

d. The drug or drugs containing such a substance are new drugs so related in their action to a drug or drugs already listed as having a potential for abuse to make it likely that the drug will have the same potentiality for abuse as such drugs, thus making it reasonable to assume that there may be significant diversions from legitimate channels, significant use contrary to or without medical advice, or that it has a substantial capability of creating hazards to the health of the user or to the safety of the community.

In the development of this scientific and medical evaluation for the purpose of scheduling, the Secretary analyzed considerable data related to the substance's abuse potential. The data include a discussion of the prevalence and frequency of use, the amount of the substance available for illicit use, the ease of obtaining or manufacturing the substance, the reputation or status of the substance ''on the street,'' and evidence relevant to at-risk populations. Importantly, the petitioners define marijuana as including all *Cannabis* cultivated strains. Different marijuana samples derived from various cultivated strains may have very different chemical constituents, thus the analysis is based on what is known about the range of these constituents across all cultivated strains.

Determining the abuse potential of a substance is complex with many dimensions, and no single test or assessment provides a complete characterization. Thus, no single measure of abuse potential is ideal. Scientifically, a comprehensive evaluation of the relative abuse potential of a substance can include consideration of the following elements: Receptor binding affinity, preclinical pharmacology, reinforcing effects, discriminative stimulus effects, dependence producing potential, pharmacokinetics, route of administration, toxicity, data on actual abuse, clinical abuse potential studies, and public health risks. Importantly, abuse can exist independently from tolerance or physical dependence because individuals may abuse drugs in doses or patterns that do not induce these phenomena. Additionally evidence of clandestine population and illicit trafficking of a substance can shed light on both the demand for a substance as well as the ease of obtaining a substance. Animal and human laboratory data and epidemiological data are all used in determining a substance's abuse potential. Moreover, epidemiological data can indicate actual abuse.

The petitioners compare the effects of marijuana to currently controlled Schedule II substances and make repeated claims about their comparative effects. Comparisons between marijuana and the diverse array of Schedule II substances is difficult, because of the pharmacologically dissimilar actions of substances of Schedule II of the CSA. For example, Schedule II substances include stimulant-like drugs (*e.g.,* cocaine, methylphenidate, and amphetamine), opioids (*e.g.,* oxycodone, fentanyl), sedatives (*e.g.,* pentobarbital, amobarbital), dissociative anesthetics (*e.g.,* PCP), and naturally occurring plant components (*e.g.,* coca leaves and poppy straw). The mechanism(s) of action of the above Schedule II substances are wholly different from one another, and they are different from tetrahydrocannabinol (THC) and marijuana as well. For example, Schedule II stimulants typically function by increasing monoaminergic tone via an increase in dopamine and norepinephrine (Schmitt et al., 2013). In contrast, opioid analgesics function via mu-opioid receptor agonist effects. These differing mechanism(s) of action result in vastly different behavioral and adverse effect profiles, making comparisons across the range of

[4] Note that ''marihuana'' is the spelling originally used in the Controlled Substances Act (CSA). This document uses the spelling that is more common in current usage, ''marijuana.''

[5] The CSA defines marijuana as the following:

All parts of the plant Cannabis Sativa L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin. Such term does not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination (21 U.S.C. 802(16)).

[6] Comprehensive Drug Abuse Prevention and Control Act of 1970, H.R. Rep. No. 91–1444, 91st Cong., Sess. 1 (1970) reprinted in U.S.C.C.A.N. 4566, 4603.

EXHIBIT 16

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1301

[Docket No. DEA–447]

Applications To Become Registered Under the Controlled Substances Act To Manufacture Marijuana To Supply Researchers in the United States

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Policy statement.

SUMMARY: To facilitate research involving marijuana and its chemical constituents, DEA is adopting a new policy that is designed to increase the number of entities registered under the Controlled Substances Act (CSA) to grow (manufacture) marijuana to supply legitimate researchers in the United States. This policy statement explains how DEA will evaluate applications for such registration consistent with the CSA and the obligations of the United States under the applicable international drug control treaty.

DATES: August 12, 2016.

FOR FURTHER INFORMATION CONTACT: Michael J. Lewis, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812.

SUPPLEMENTARY INFORMATION:

Background

Reasons for This Policy Statement

There is growing public interest in exploring the possibility that marijuana or its chemical constituents may be used as potential treatments for certain medical conditions. The Federal Food, Drug and Cosmetic Act requires that before a new drug is allowed to enter the U.S. market, it must be demonstrated through adequate and well-controlled clinical trials to be both safe and effective for its intended uses. Congress long ago established this process, recognizing that it was essential to protect the health and welfare of the American people.

Although no drug product made from marijuana has yet been shown to be safe and effective in such clinical trials, DEA—along with the Food and Drug Administration (FDA) and the National Institutes of Health (NIH)—fully supports expanding research into the potential medical utility of marijuana and its chemical constituents.[1]

There are a variety of factors that influence whether and to what extent such research takes place. Some of the key factors—such as funding—are beyond DEA's control.[2] However, one of the ways DEA can help to facilitate research involving marijuana is to take steps, within the framework of the CSA and U.S. treaty obligations, to increase the lawful supply of marijuana available to researchers.

For nearly 50 years, the United States has relied on a single grower to produce marijuana used in research. This grower operates under a contract with the National Institute on Drug Abuse (NIDA). This longstanding arrangement has historically been considered by the U.S. Government to be the best way to satisfy our nation's obligations under the applicable international drug control treaty, as discussed in more detail below. For most of the nearly 50 years that this single marijuana grower arrangement has been in existence, the demand for research-grade marijuana in the United States was relatively limited—and the single grower was able to meet such limited demand. However, in recent years, there has been greater public interest in expanding marijuana-related research, particularly with regard to certain chemical constituents in the plant known as cannabinoids.

The term ''cannabinoids'' generally refers to those chemicals unique to the cannabis plant (marijuana).[3] To date, more than 100 different cannabinoids have been found in the plant. One such cannabinoid—known as cannabidiol or CBD—has received increased attention in recent years. Although the effects of CBD are not yet fully understood by scientists, and research is ongoing in this area, some studies suggest that CBD may have uses in the treatment of seizures and other neurological disorders. A growing number of researchers have expressed interest in conducting research with extracts of marijuana that have a particular percentage of CBD and other cannabinoids. DEA fully supports research in this area. Based on discussions with NIDA and FDA, DEA has concluded that the best way to satisfy the current researcher demand for a variety of strains of marijuana and cannabinoid extracts is to increase the number of federally authorized marijuana growers. To achieve this result, DEA, in consultation with NIDA and FDA, has developed a new approach to allow additional marijuana growers to apply to become registered with DEA, while upholding U.S. treaty obligations and the CSA. This policy statement explains the new approach, provides details about the process by which potential growers may apply for a DEA registration, and describes the steps they must take to ensure their activity will be carried out in conformity with U.S. treaty obligations and the CSA.

The historical system, under which NIDA relied on one grower to supply marijuana on a contract basis, was designed primarily to supply marijuana for use in federally funded research—not for commercial product development. Thus, under the historical system, there was no clear legal pathway for commercial enterprises to produce marijuana for product development. In contrast, under the new approach explained in this policy statement, persons may become registered with DEA to grow marijuana not only to supply federally funded or other academic researchers, but also for strictly commercial endeavors funded by the private sector and aimed at drug product development. Likewise, under the new approach, should the state of scientific knowledge advance in the future such that a marijuana-derived drug is shown to be safe and effective for medical use, pharmaceutical firms will have a legal means of producing such drugs in the United States—independent of the NIDA contract process.

Legal Considerations

Applicable CSA Provisions

Under the CSA, all persons who seek to manufacture or distribute a controlled substance must apply for a DEA registration. 21 U.S.C. 822(a)(1). Applications by persons seeking to grow

[1] There are two FDA-approved drugs that contain a synthetic form of dronabinol, which is one of the chemicals found in marijuana. These drugs are Marinol (which the FDA approved for the treatment of nausea and vomiting associated with cancer chemotherapy, and for the treatment of anorexia associated with weight loss in patients with AIDS) and Syndros (which was approved for the same indications as Marinol).

[2] Funding may actually be the most important factor in whether research with marijuana (or any other experimental drug) takes place. What appears to have been the greatest spike in marijuana research in the United States occurred shortly after the State of California enacted legislation in 1999 to fund such research. Specifically, in 1999, California enacted a law that established the ''California Marijuana Research Program'' to develop and conduct studies on the potential medical utility of marijuana. Cal. Health & Safety Code § 11362.9. The state legislature appropriated a total of $9 million for the marijuana research studies. Over the next five years, DEA received applications for registration in connection with at least 17 State-sponsored pre-clinical or clinical studies of marijuana (all of which DEA granted). 74 FR 2101, 2105 (2009). However, it appears that once the State stopped funding the research, the studies ended.

[3] An acceptable and broader definition of ''cannabinoids'' includes not only those chemicals unique to the cannabis plant but also their derivatives and transformation products.

marijuana to supply researchers are governed by 21 U.S.C. 823(a); *see generally* 76 FR 51403 (2011); 74 FR 2101 (2009). Under section 823(a), for DEA to grant a registration, two conditions must be satisfied: (1) The registration must be consistent with the public interest (based on the enumerated criteria listed in section 823(a)) and (2) the registration must be consistent with U.S. obligations under the Single Convention on Narcotic Drugs, 1961 (Single Convention). An applicant seeking registration under section 823(a) has ''the burden of proving that the requirements for such registration pursuant to [this section] are satisfied.'' 21 CFR 1301.44(a). Although each application for registration that DEA receives will be evaluated individually based on its own merit, some general considerations warrant mention here.

First, while it is DEA's intention to increase the number of registered marijuana growers who will be supplying U.S. researchers, the CSA does not authorize DEA to register an unlimited number of manufacturers. As subsection 823(a)(1) provides, DEA is obligated to register only the number of bulk manufacturers of a given schedule I or II controlled substance that is necessary to ''produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes.'' *See* 74 FR at 2127–2130 (discussing meaning of subsection 823(a)(1)). This provision is based on the long-established principle that having fewer registrants of a given controlled substances tends to decrease the likelihood of diversion.

Consistent with subsection 823(a)(1), DEA will evaluate each application it receives to determine whether adding such applicant to the list of registered growers is necessary to provide an adequate and uninterrupted supply of marijuana (including extracts and other derivatives thereof) to researchers in the United States.[4]

Second, as with any application submitted pursuant to section 823(a), in determining whether the proposed registration would be consistent with the public interest, among the factors to be considered are whether the applicant has previous experience handling controlled substances in a lawful manner and whether the applicant has engaged in illegal activity involving controlled substances. In this context, illegal activity includes any activity in violation of the CSA (regardless of whether such activity is permissible under State law) as well as activity in violation of State or local law. While past illegal conduct involving controlled substances does not automatically disqualify an applicant, it may weigh heavily against granting the registration.

Third, given the in-depth nature of the analysis that the CSA requires DEA to conduct in evaluating these applications, applicants should anticipate that, in addition to the information requested in the application itself, they will be asked to submit other information germane to the application in accordance with 21 CFR 1301.15. This will include, among other things, detailed information regarding an applicant's past experience in the manufacture of controlled substances. In addition, applicants will be asked to provide a written explanation of how they believe they would be able to augment the nation's supply of research-grade marijuana within the meaning of subsection 823(a)(1). Applicants may be asked to provide additional written support for their application and other information that DEA deems relevant in evaluating the application under section 823(a).

Treaty Considerations

As stated above, DEA may only issue a registration to grow marijuana to supply researchers if the registration is consistent with U.S. obligations under the Single Convention. Although this policy document will not list all of the applicable requirements of the Single Convention,[5] the following is a summary of some of the key considerations.

Under articles 23 and 28 of the Single Convention, a party (*i.e.,* a country that is a signatory to the treaty) that allows the cultivation of cannabis for lawful uses (*e.g.,* FDA-authorized clinical trials) must:

(a) Designate the areas in which, and the plots of land on which, cultivation of the cannabis plant for the purpose of producing cannabis shall be permitted;

(b) License cultivators authorized to cultivate cannabis;

(c) Specify through such licensing the extent of the land on which the cultivation is permitted;

(d) Purchase and take physical possession of all cannabis crops from all cultivators as soon as possible, but not later than four months after the end of the harvest; and

(e) Have the exclusive right of importing, exporting, wholesale trading and maintaining stocks of cannabis.

As DEA has stated in a prior publication, DEA carries out those functions of article 23, paragraph 2, that are encompassed by the DEA registration system (paragraphs (a) through (c) above), and NIDA carries out those functions relating to purchasing the marijuana and maintaining a monopoly over the wholesale distribution (paragraphs (d) and (e) above).[6] 76 FR at 51409.

As indicated, DEA's historical approach to ensuring compliance with the foregoing treaty requirements was to limit the registration of marijuana growers who supply researchers to those entities that operate under a contract with NIDA. Under this historical approach, the grower could be considered an extension of NIDA and thus all marijuana produced by the grower was effectively owned by NIDA, with NIDA controlling all distribution to researchers.

However, as further indicated, DEA has concluded, based on discussions with NIDA and FDA, that it would be beneficial for research to allow additional marijuana growers outside the NIDA-contract system, provided this could be accomplished in a manner consistent with the CSA and the treaty. Toward this end, DEA took into account the following statement contained in the official commentary to the Single Convention:

> Countries . . . which produce . . . cannabis . . . , [i]n so far as they permit private farmers to cultivate the plants . . . , cannot establish with sufficient exactitude the quantities harvested by individual producers. If they allowed the sale of the crops to private traders, they would not be in a position to ascertain with reasonable exactitude the amounts which enter their controlled trade. The effectiveness of their control régime would thus be considerably weakened. In fact, experience has shown that permitting licensed private traders to purchase the crops results in diversion of large quantities of drugs into illicit channels. . . . [T]he acquisition of the crops and the wholesale and international trade in these agricultural products cannot be entrusted to private traders, but must be undertaken by governmental authorities in the producing countries. Article 23 . . . and article 28 . . . therefore require a government monopoly of the wholesale and international trade in the agricultural product in question in the country which authorizes its production.
>
> Commentary at 278

[4] In making this determination, DEA will consult with NIH and FDA, as warranted.

[5] A detailed explanation of the relevant Single Convention requirements can be found in 74 FR at 2114–2118.

[6] In accordance with the CSA, DEA carries out functions that are indirectly related to those specified in article 23, paragraph 2(e). For example, DEA controls imports and exports of cannabis through the CSA registration and permitting system.

Given the foregoing considerations, DEA believes it would be consistent with the purposes of articles 23 and 28 of the Single Convention for DEA to register marijuana growers outside of the NIDA-contract system to supply researchers, *provided the growers agree that they may only distribute marijuana with prior, written approval from DEA.* In other words, in lieu of requiring the growers to operate under a contract with NIDA, a registered grower will be permitted to operate independently, provided the grower agrees (through a written memorandum of agreement with DEA) that it will only distribute marijuana with prior, written approval from DEA. DEA believes this new approach will succeed in avoiding one of the scenarios the treaty is designed to prevent: Private parties trading in marijuana outside the supervision or direction of the federal government.

Also, consistent with the purposes and structure of the CSA, persons who become registered to grow marijuana to supply researchers will only be authorized to supply DEA-registered researchers whose protocols have been determined by the Department of Health and Human Services (HHS) to be scientifically meritorious. *See* 21 U.S.C. 823(f). In 2015, HHS announced the details of its current policy for evaluating the merits of research protocols involving marijuana. 80 FR 35960 (2015).

Finally, potential applicants should note that any entity granted a registration to manufacture marijuana to supply researchers will be subject to all applicable requirements of the CSA and DEA regulations, including those relating to quotas, record keeping, order forms, security, and diversion control.

How To Apply for a Registration

Persons interested in applying for a registration to become a bulk manufacturer of marijuana to supply legitimate researchers can find instructions and the application form by going to the DEA Office of Diversion Control Web site registration page at *www.deadiversion.usdoj.gov/drugreg/index.html#regapps.* Applicants will need to submit Form 225.

Note Regarding the Nature of This Document

This document is a general statement of DEA policy. While this document reflects how DEA intends to implement the relevant statutory and regulatory provisions, it does not establish a rule that is binding on any member of the public. Any person who applies for a registration to grow marijuana (as with any other applicant for registration under the CSA) is entitled to due process in the consideration of the application by the Agency. To ensure such due process, the CSA provides that, before taking action to deny an application for registration, DEA must serve upon the applicant an order to show cause why the application should not be denied, which shall provide the applicant with an opportunity to request a hearing on the application in accordance with the Administrative Procedure Act. 21 U.S.C. 824(c).

Dated: July 25, 2016.

Chuck Rosenberg,

Acting Administrator.

[FR Doc. 2016–17955 Filed 8–11–16; 8:45 am]

BILLING CODE 4410–09–P

EXHIBIT 17

blessed are those who are persecuted because of righteousness, for theirs is the kingdom of Heaven. Let us now work to bring that kingdom of Heaven closer to Earth.

RECESS

The SPEAKER pro tempore. Pursuant to clause 12(a) of rule I, the Chair declares the House in recess until 2 p.m. today.

Accordingly (at 12 o'clock and 6 minutes p.m.), the House stood in recess.

□ 1400

AFTER RECESS

The recess having expired, the House was called to order by the Speaker pro tempore (Mr. DENHAM) at 2 p.m.

PRAYER

The Chaplain, the Reverend Patrick J. Conroy, offered the following prayer:

Gracious God, we give You thanks for giving us another day. In this Chamber where the people's House gathers, we pause to offer You gratitude for the gift of this good land on which we live and for this great Nation which You have inspired in developing over so many years. Continue to inspire the American people that, through the difficulties of these days, we might keep liberty and justice alive in our Nation and in the world.

A week after many Members of this assembly traveled to Selma to remember historic and heroic actions 50 years ago, may the House be energized to guarantee the very rights so many suffered to obtain back then and which still elude so many of their American descendants today.

May all that is done this day be for Your greater honor and glory.

Amen.

THE JOURNAL

The SPEAKER pro tempore. The Chair has examined the Journal of the last day's proceedings and announces to the House his approval thereof.

Pursuant to clause 1, rule I, the Journal stands approved.

PLEDGE OF ALLEGIANCE

The SPEAKER pro tempore. Will the gentleman from Michigan (Mr. KILDEE) come forward and lead the House in the Pledge of Allegiance.

Mr. KILDEE led the Pledge of Allegiance as follows:

I pledge allegiance to the Flag of the United States of America, and to the Republic for which it stands, one nation under God, indivisible, with liberty and justice for all.

ANOTHER OBAMACARE DEBACLE

(Ms. FOXX asked and was given permission to address the House for 1 minute.)

Ms. FOXX. Mr. Speaker, last month, the Obama administration admitted that it sent inaccurate tax forms to 820,000 Americans who receive health insurance through ObamaCare. Individuals who received subsidies must fill out the 1095–A form to document what they have received for the past year.

The government is advising people not to file their tax returns until they have the correct forms, but just last week Kevin Counihan, the man responsible and accountable for leading healthcare.gov, declined to say when ObamaCare participants will get the correct tax forms and if all of the new forms have been created.

Since its implementation, the President's health care law has proved to be a hindrance, not a help, to the health care market. This debacle is yet another example of why we must continue to work towards repealing this ill-conceived law and replacing it with policies that empower patients and promote access to affordable health care options.

JOBS

(Mr. KILDEE asked and was given permission to address the House for 1 minute.)

Mr. KILDEE. Well, Mr. Speaker, I just got back from spending a week at home in Michigan talking with the people that I work for and meeting with small business owners. I heard a lot of frustration—frustration about the priorities of the Republican leadership in the House and of Congress in general.

Instead of legislation to create jobs here in America to make it easier for hardworking families to buy their own home, to afford to send their kids to school, and to save for retirement, this Congress has bounced from one manufactured political crisis to the next and has not taken on the big challenges that the people sent us here to take on.

Let's put away this dysfunction and this paralysis. Let's get back to the work of the American people.

As we now are set to consider our Nation's budget, let's make sure that the priorities of the American people—good paying jobs, affordable college, homeownership, and the ability to save for a decent retirement—that those priorities are the priorities that we include in this important budget document. This is what the American people expect of us, and this is what we should take on.

COMMUNICATION FROM THE CLERK OF THE HOUSE

The SPEAKER pro tempore laid before the House the following communication from the Clerk of the House of Representatives:

OFFICE OF THE CLERK,
HOUSE OF REPRESENTATIVES,
Washington, DC, March 16, 2015.

Hon. JOHN A. BOEHNER,
The Speaker, House of Representatives, Washington, DC.

DEAR MR. SPEAKER: Pursuant to the permission granted in Clause 2(h) of Rule II of the Rules of the U.S. House of Representatives, the Clerk received the following message from the Secretary of the Senate on March 16, 2015 at 10:38 a.m.:

That the Senate agreed to S. Con. Res. 7.

With best wishes, I am

Sincerely,

ROBERT F. REEVES,
Deputy Clerk.

RECESS

The SPEAKER pro tempore. Pursuant to clause 12(a) of rule I, the Chair declares the House in recess subject to the call of the Chair.

Accordingly (at 2 o'clock and 5 minutes p.m.), the House stood in recess.

□ 1530

AFTER RECESS

The recess having expired, the House was called to order by the Speaker pro tempore (Mr. DUNCAN of Tennessee) at 3 o'clock and 30 minutes p.m.

ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore. Pursuant to clause 8 of rule XX, the Chair will postpone further proceedings today on motions to suspend the rules on which a recorded vote or the yeas and nays are ordered, or on which the vote incurs objection under clause 6 of rule XX.

Record votes on postponed questions will be taken later.

IMPROVING REGULATORY TRANSPARENCY FOR NEW MEDICAL THERAPIES ACT

Mr. PITTS. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 639) to amend the Controlled Substances Act with respect to drug scheduling recommendations by the Secretary of Health and Human Services, and with respect to registration of manufacturers and distributors seeking to conduct clinical testing, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 639

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Improving Regulatory Transparency for New Medical Therapies Act''.

SEC. 2. SCHEDULING OF SUBSTANCES INCLUDED IN NEW FDA-APPROVED DRUGS.

(a) EFFECTIVE DATE OF APPROVAL.—

(1) EFFECTIVE DATE OF DRUG APPROVAL.—Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended by adding at the end the following:

''(x) DATE OF APPROVAL IN THE CASE OF RECOMMENDED CONTROLS UNDER THE CSA.—

''(1) IN GENERAL.—In the case of an application under subsection (b) with respect to a drug for which the Secretary provides notice to the sponsor that the Secretary intends to recommend controls under the Controlled Substances Act, approval of such application shall not take effect until the interim final rule controlling the drug is issued in accordance with section 201(j) of the Controlled Substances Act.

''(2) DATE OF APPROVAL.—For purposes of this section, with respect to an application described in paragraph (1), the term 'date of approval' shall mean the later of—

''(A) the date an application under subsection (b) is approved under subsection (c); or

''(B) the date of issuance of the interim final rule controlling the drug.''.

(2) EFFECTIVE DATE OF APPROVAL OF BIOLOGICAL PRODUCTS.—Section 351 of the Public Health Service Act (42 U.S.C. 262) is amended by adding at the end the following:

''(n) DATE OF APPROVAL IN THE CASE OF RECOMMENDED CONTROLS UNDER THE CSA.—

''(1) IN GENERAL.—In the case of an application under subsection (a) with respect to a biological product for which the Secretary provides notice to the sponsor that the Secretary intends to recommend controls under the Controlled Substances Act, approval of such application shall not take effect until the interim final rule controlling the biological product is issued in accordance with section 201(j) of the Controlled Substances Act.

''(2) DATE OF APPROVAL.—For purposes of this section, with respect to an application described in paragraph (1), references to the date of approval of such application, or licensure of the product subject to such application, shall mean the later of—

''(A) the date an application is approved under subsection (a); or

''(B) the date of issuance of the interim final rule controlling the biological product.''.

(3) EFFECTIVE DATE OF APPROVAL OF ANIMAL DRUGS.—

(A) IN GENERAL.—Section 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b) is amended by adding at the end the following:

''(q) DATE OF APPROVAL IN THE CASE OF RECOMMENDED CONTROLS UNDER THE CSA.—

''(1) IN GENERAL.—In the case of an application under subsection (b) with respect to a drug for which the Secretary provides notice to the sponsor that the Secretary intends to recommend controls under the Controlled Substances Act, approval of such application shall not take effect until the interim final rule controlling the drug is issued in accordance with section 201(j) of the Controlled Substances Act.

''(2) DATE OF APPROVAL.—For purposes of this section, with respect to an application described in paragraph (1), the term 'date of approval' shall mean the later of—

''(A) the date an application under subsection (b) is approved under subsection (c); or

''(B) the date of issuance of the interim final rule controlling the drug.''.

(B) CONDITIONAL APPROVAL.—Section 571(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ccc(d)) is amended by adding at the end the following:

''(4)(A) In the case of an application under subsection (a) with respect to a drug for which the Secretary provides notice to the sponsor that the Secretary intends to recommend controls under the Controlled Substances Act, conditional approval of such application shall not take effect until the interim final rule controlling the drug is issued in accordance with section 201(j) of the Controlled Substances Act.

''(B) For purposes of this section, with respect to an application described in subparagraph (A), the term 'date of approval' shall mean the later of—

''(i) the date an application under subsection (a) is conditionally approved under subsection (b); or

''(ii) the date of issuance of the interim final rule controlling the drug.''.

(C) INDEXING OF LEGALLY MARKETED UNAPPROVED NEW ANIMAL DRUGS.—Section 572 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ccc–1) is amended by adding at the end the following:

''(k) In the case of a request under subsection (d) to add a drug to the index under subsection (a) with respect to a drug for which the Secretary provides notice to the person filing the request that the Secretary intends to recommend controls under the Controlled Substances Act, a determination to grant the request to add such drug to the index shall not take effect, and the Secretary shall not list the drug on such index, until the interim final rule controlling the drug is issued in accordance with section 201(j) of the Controlled Substances Act.''.

(4) DATE OF APPROVAL FOR DESIGNATED NEW ANIMAL DRUGS.—Section 573(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ccc–2(c)) is amended by adding at the end the following:

''(3) For purposes of determining the 7-year period of exclusivity under paragraph (1) for a drug for which the Secretary intends to recommend controls under the Controlled Substances Act, the drug shall not be considered approved or conditionally approved until the date that the interim final rule controlling the drug is issued in accordance with section 201(j) of the Controlled Substances Act.''.

(b) SCHEDULING OF NEWLY APPROVED DRUGS.—Section 201 of the Controlled Substances Act (21 U.S.C. 811) is amended by inserting after subsection (i) the following:

''(j)(1) With respect to a drug referred to in subsection (f), if the Secretary of Health and Human Services recommends that the Attorney General add the drug to schedule II, III, IV, or V pursuant to subsections (a) and (b), the Attorney General shall, not later than 90 days after the date described in paragraph (2), issue an interim final rule controlling the drug in accordance with such subsections and section 202(b) using the procedures described in paragraph (3).

''(2) The date described in this paragraph shall be the later of—

''(A) the date on which the Attorney General receives the scientific and medical evaluation and recommendations from the Secretary of Health and Human Services in accordance with subsection (b); or

''(B) the date on which the Attorney General receives notification from the Secretary of Health and Human Services that the Secretary has approved an application under section 505(c), 512, 571, or 572 of the Federal Food, Drug, and Cosmetic Act or section 351(a) of the Public Health Service Act with respect to the drug described in paragraph (1).

''(3) A rule issued by the Attorney General under paragraph (1) shall be in accordance with the procedures provided in subsection (a), except that the rule shall become immediately effective as an interim final rule without requiring the Attorney General to demonstrate good cause therefor. After publication of the interim final rule, the Attorney General shall issue a final rule in accordance with the procedures provided in subsection (a).''.

(c) EXTENSION OF PATENT TERM.—Section 156 of title 35, United States Code, is amended—

(1) in subsection (d)(1), in the matter preceding subparagraph (A), by inserting '', or in the case of a drug product described in subsection (i) within the sixty-day period beginning on the covered date (as defined in subsection (i))'' after ''marketing or use''; and

(2) by adding at the end the following:

''(i)(1) For purposes of this section, if the Secretary of Health and Human Services provides notice to the sponsor of an application or request for approval, conditional approval, or indexing of a drug product for which the Secretary intends to recommend controls under the Controlled Substances Act, beginning on the covered date, the drug product shall be considered to—

''(A) have been approved under the relevant provision of the Public Health Service Act or Federal Food, Drug, and Cosmetic Act; and

''(B) have permission for commercial marketing or use.

''(2) In this subsection, the term 'covered date' means the later of—

''(A) the date an application is approved—

''(i) under section 351(a)(2)(C) of the Public Health Service Act; or

''(ii) under section 505(b) or 512(c) of the Federal Food, Drug, and Cosmetic Act;

''(B) the date an application is conditionally approved under section 571(b) of the Federal Food, Drug, and Cosmetic Act;

''(C) the date a request for indexing is granted under section 572(d) of the Federal Food, Drug, and Cosmetic Act; or

''(D) the date of issuance of the interim final rule controlling the drug under section 201(j) of the Controlled Substances Act.''.

SEC. 3. ENHANCING NEW DRUG DEVELOPMENT.

Section 303 of the Controlled Substances Act (21 U.S.C. 823) is amended by adding at the end the following:

''(i)(1) For purposes of registration to manufacture a controlled substance under subsection (d) for use only in a clinical trial, the Attorney General shall register the applicant, or serve an order to show cause upon the applicant in accordance with section 304(c), not later than 180 days after the date on which the application is accepted for filing.

''(2) For purposes of registration to manufacture a controlled substance under subsection (a) for use only in a clinical trial, the Attorney General shall, in accordance with the regulations issued by the Attorney General, issue a notice of application not later than 90 days after the application is accepted for filing. Not later than 90 days after the date on which the period for comment pursuant to such notice ends, the Attorney General shall register the applicant, or serve an order to show cause upon the applicant in accordance with section 304(c), unless the Attorney General has granted a hearing on the application under section 1008(i) of the Controlled Substances Import and Export Act.''.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Pennsylvania (Mr. PITTS) and the gentleman from Texas (Mr. GENE GREEN) each will control 20 minutes.

The Chair recognizes the gentleman from Pennsylvania.

GENERAL LEAVE

Mr. PITTS. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days in which to revise and extend their remarks and insert extraneous materials into the RECORD on the bill.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Pennsylvania?

There was no objection.

Mr. PITTS. Mr. Speaker, I yield myself such time as I may consume.

I will include an exchange of letters between the Committee on Energy and Commerce and the Committee on the Judiciary.

Mr. Speaker, H.R. 639 seeks to improve the transparency and consistency of the Drug Enforcement Administration's first scheduling of new FDA-approved drugs under the Controlled Substances Act, the CSA, and, secondly, its registration process for the manufacture of controlled substances for use in clinical trials. Ultimately, this will allow new and innovative treatments to get to patients who desperately need them.

Due to the cost and uncertainty of the drug development process, there is broad agreement that a predictable timeline for approval decisions is a necessary component to successful drug development.

Industry, the FDA, and Congress have taken steps to provide more transparency and consistency in the drug approval process through the negotiation and authorization of the Prescription Drug User Fee program and a commitment to review goals embedded in the PDUFA agreements.

However, drugs that contain substances that have not been previously marketed in the U.S. and that have abuse potential must also be scheduled under the Controlled Substances Act, the CSA, by the DEA before they can reach patients.

Under the CSA, there is no deadline for the DEA to make a scheduling decision, and the delays in DEA decisions have increased significantly. Between 1997 and 1999 and 2009 and 2013, the average time between FDA approval and DEA's final scheduling increased from an average of 49.3 days to an average of 237.6 days. Recently, a company had to wait over 13 months after FDA approval to receive a final scheduling recommendation from the DEA.

The lack of predictability in the timing of DEA scheduling decisions leads to unnecessary uncertainty in the drug development process and needless delays in patient access to new therapies.

Section 2 of H.R. 639, as amended by the full committee, would require DEA to issue an interim final rule, scheduling the new drug no later than 90 days after it is approved or when it receives the FDA's scheduling recommendation, whichever comes later. After receiving the FDA's recommendation, the DEA would continue to conduct its own analysis prior to scheduling the drug, but patients would now have peace of mind in knowing this will no longer be an open-ended process. Of note: since 1996, the DEA has not made any scheduling decision for a new drug that was contrary to the FDA recommendation.

Further, section 3 of this bill would bring much-needed certainty to another open-ended DEA process. Manufacturers of controlled substances are required to be registered with the DEA. The requirement to register extends to manufacturers of controlled substances intended to be used in clinical trials for products not yet approved by the FDA. There is no timetable for the DEA to grant approval of registration applications, and there is not a process for the applicant to determine the reasons for delay in the application. The lack of transparency, predictability, and timeliness in the registration process leaves companies unable to properly plan clinical trial schedules for prospective new therapies.

For registration applications related to schedule III, IV, and V drugs that will only be used in clinical trials, section 3, as amended by the full committee, would require the DEA to register the applicant or serve an order to show cause on why the applicant shall not be registered within 180 days of the filing of the application.

For drugs in schedule I and II that will only be used in a clinical trial, the DEA would be required to issue a notice of application not later than 90 days after an application is accepted for filing. Ninety days after the end of the comment period, pursuant to the notice, the DEA would be required to register the applicant or serve an order to show cause on why the registrant should not be registered.

Such a solution does not force the DEA to make a particular decision but will provide transparency to the process so companies can better plan when regulatory decisions will be made.

I would urge all Members to support this critical piece of legislation.

I reserve the balance of my time.

HOUSE OF REPRESENTATIVES,
COMMITTEE ON THE JUDICIARY,
March 16, 2015.

Hon. FRED UPTON,
Chairman, Committee on Energy and Commerce, Rayburn House Office Building, Washington, DC.

DEAR CHAIRMAN UPTON: I am writing with respect to H.R. 639, the ''Improving Regulatory Transparency for New Medical Therapies Act.'' As a result of your having consulted with us on provisions in H.R. 639 that fall within the Rule X jurisdiction of the Committee on the Judiciary, I agree to discharge our Committee from further consideration of this bill so that it may proceed expeditiously to the House floor for consideration.

The Judiciary Committee takes this action with our mutual understanding that by foregoing consideration of H.R. 639 at this time, we do not waive any jurisdiction over subject matter contained in this or similar legislation, and that our Committee will be appropriately consulted and involved as this bill or similar legislation moves forward so that we may address any remaining issues in our jurisdiction. Our Committee also reserves the right to seek appointment of an appropriate number of conferees to any House-Senate conference involving this or similar legislation, and asks that you support any such request.

I would appreciate a response to this letter confirming this understanding with respect to H.R. 639, and would ask that a copy of our exchange of letters on this matter be included in the Congressional Record during Floor consideration of H.R. 639.

Sincerely,

BOB GOODLATTE,
Chairman.

HOUSE OF REPRESENTATIVES,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC, March 16, 2015.

Hon. BOB GOODLATTE,
Chairman, Committee on the Judiciary, Rayburn House Office Building Washington, DC.

DEAR CHAIRMAN GOODTETTE: Thank you for your letter regarding H.R. 639, the ''Improving Regulatory Transparency for New Medical Therapies Act.'' As you noted, there are provisions of the bill that fall within the Committee on the Judiciary's Rule X jurisdiction.

I appreciate your willingness to forgo action on H.R. 639, and I agree that your decision is not a waiver of any of the Committee on the Judiciary's jurisdiction over the subject matter contained in this or similar legislation, and that the Committee will be consulted appropriately and involved as the bill or similar legislation moves forward. In addition, I understand the Committee reserves the right to seek the appointment of an appropriate number of conferees to any House-Senate conference involving this or similar legislation, for which you will have my support.

I will include a copy of your letter and this response in the Congressional Record during consideration of H.R. 639 on the House floor.

Sincerely,

FRED UPTON,
Chairman.

Mr. GENE GREEN of Texas. Mr. Speaker, I yield myself as much time as I may consume.

Mr. Speaker, I rise in support of H.R. 639, the Improving Regulatory Transparency for New Medical Therapies Act. This legislation was introduced by the chair of our Health Subcommittee, JOE PITTS of Pennsylvania; the ranking member of the full committee, FRANK PALLONE of New Jersey; and myself to provide a solution to delays experienced by patients in need.

Currently, new drugs and substances that previously have not been marketed in the United States and that have abuse potential must be scheduled by the Drug Enforcement Administration prior to being marketed.

The amount of time the DEA has taken before acting on FDA recommendations has significantly lengthened in recent years, which delays the availability of new therapies.

This legislation will improve patient access by bringing clarity and transparency to the process of scheduling a new FDA-approved therapy.

I was pleased to join the gentleman from Pennsylvania (Mr. PITTS) and the gentleman from New Jersey (Mr. PALLONE) in supporting this legislation to continue the great work they started last Congress. I thank them and their staff for working on this important access issue.

I want to acknowledge the leadership of Chairman UPTON and the work of the committee's minority and majority staff in advancing this bill through the Energy and Commerce Committee. I

support this bipartisan bill and urge my colleagues to do the same.

Mr. Speaker, I yield back the balance of my time.

Mr. PITTS. Mr. Speaker, I urge all Members to support this bipartisan legislation, and I yield back the balance of my time.

Mr. BURGESS. Mr. Speaker, I would like to submit the cost estimate prepared by the Congressional Budget Office for H.R. 639.

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, March 16, 2015.

Hon. FRED UPTON,
Chairman, Committee on Energy and Commerce, House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 639, the Improving Regulatory Transparency for New Medical Therapies Act.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Julia Christensen.

Sincerely,

DOUGLAS W. ELMENDORF.

Enclosure.

AS ORDERED REPORTED BY THE HOUSE COMMITTEE ON ENERGY AND COMMERCE ON FEBRUARY 12, 2015

H.R. 639 would modify the administrative procedures followed by the Department of Justice in regulating new drugs that are already approved by the Food and Drug Administration (FDA) and in authorizing drugs to be used in clinical trials. The legislation would aim to streamline the current review and approval process. CBO estimates that implementing the bill would have no significant effect on spending subject to appropriation. Enacting the legislation would affect direct spending and revenues related to federal health care costs; therefore, pay-as-you-go procedures apply. CBO estimates that that those effects would also not be significant over the 2015–2025 period.

The legislation would change the effective date of FDA approval for certain new drugs that undergo review by the Drug Enforcement Agency (DEA) to determine if the drug should be marketed with restrictions as a controlled substance. Such a change could extend certain regulatory periods during which FDA will not accept marketing applications or permit another manufacturer to market a version of an affected drug and could also result in the extension of patent terms for certain products. Extending such periods of marketing exclusivity could delay the entry of lower-priced generic drugs on the market, and such a delay would increase the average cost for prescription drugs. Any increase in health care costs resulting from delaying the market entry of generic drugs would affect direct spending and revenues by increasing the cost of prescription drugs for federal health programs and private health insurance.

CBO expects that the bill's provisions would apply to a limited number of drugs subject to DEA classification after enactment. Because most drugs generally retain patent protections after FDA approval for more than 10 years, CBO anticipates that the likelihood that drugs affected by the bill will face generic competition before 2025 under current law would be small. As a result, we estimate that enacting the bill would not significantly affect direct spending or revenues over the 2015–2025 period. Beyond 2025, however, the potential for the legislation to delay the market entry of generic drugs would be greater, and the effect on direct spending and revenues would increase in later years.

H.R. 639 contains no intergovernmental mandates as defined in the Unfunded Mandates Reform Act (UMRA) and would impose no costs on state, local, or tribal governments. The bill would impose a private-sector mandate, as defined under UMRA, on manufacturers of generic drugs by delaying the entry of those products in the market. The cost of the mandate would be the net loss of income, which could be significant depending on the drug. Based on information from industry sources, CBO estimates that the cost of the mandate would probably fall below the annual threshold established in UMRA for private-sector mandates ($154 million in 2015, adjusted annually for inflation).

The CBO staff contacts for this estimate are Julia Christensen and Mark Grabowicz (for federal costs) and Amy Petz (for private sector costs). The estimate was approved by Theresa Gullo, Deputy Assistant Director for Budget Analysis.

Mr. PALLONE. Mr. Speaker, I am pleased to lend my support to H.R. 639, the Improving Regulatory Transparency for New Medical Therapies Act. This important public health bill aims to bring better reliability and transparency to medical therapies, while continuing to ensure that they reach patients in need quickly, but most importantly safely and effectively.

When a new drug is approved by the FDA, a company can begin marketing the product upon its approval. However, for a subset of drugs, FDA recommends to the DEA they be included in the Controlled Substance Act—or "scheduled," if there is abuse potential. Until DEA makes a final decision, a drug cannot be released to the public.

Unfortunately, there is no deadline for the DEA to make a decision. As a result, the process has lengthened over time, in some instances lasting years before a decision is made. So even if a drug is considered safe and effective, patients and physicians are being forced to wait to access these therapies. This bill would continue to allow DEA to conduct its own analysis, but would remove much of the uncertainty from the process. It also would speed up the DEA registration process allowing the manufacture and distribution of controlled substances for use only in clinical trials.

I want to thank Chairman PITTS for working with me on this bill last Congress, and committing to move forward early this Congress. Thank you to Mr. GREEN as well for joining us on this important bill.

I am glad that we have been able to work with both DEA and FDA, our Senate counterparts and the bill sponsors, to ensure that the goals of this bill is met.

I urge members to support H.R 639 and I look forward to its swift passage.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Pennsylvania (Mr. PITTS) that the House suspend the rules and pass the bill, H.R. 639, as amended.

The question was taken; and (two-thirds being in the affirmative) the rules were suspended and the bill, as amended, was passed.

A motion to reconsider was laid on the table.

ACCESS TO LIFE-SAVING TRAUMA CARE FOR ALL AMERICANS ACT

Mr. BURGESS. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 647) to amend title XII of the Public Health Service Act to reauthorize certain trauma care programs, and for other purposes.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 647

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Access to Life-Saving Trauma Care for All Americans Act''.

SEC. 2. REAUTHORIZATION OF TRAUMA AND EMERGENCY CARE PROGRAMS.

(a) TRAUMA CENTER CARE GRANTS.—Section 1245 of the Public Health Service Act (42 U.S.C. 300d–45) is amended in the first sentence—

(1) by striking ''2009, and such'' and inserting ''2009, such''; and

(2) by inserting before the period at the end the following: '', and $100,000,000 for each of fiscal years 2016 through 2020''.

(b) TRAUMA SERVICE AVAILABILITY GRANTS.—Section 1282 of the Public Health Service Act (42 U.S.C. 300d–82) is amended by striking ''2015'' and inserting ''2020''.

SEC. 3. ALIGNMENT OF PROGRAMS UNDER ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE.

Section 2811(c)(2)(F) of the Public Health Service Act (42 U.S.C. 300hh–10(c)(2)(F)) is amended by striking ''trauma care under parts A through C of title XII'' and inserting ''trauma care under parts A through D of title XII and part H of such title''.

SEC. 4. TECHNICAL CORRECTIONS RELATING TO TRAUMA CENTER GRANTS.

(a) CLARIFICATION ON ELIGIBLE TRAUMA CENTERS.—Section 1241(a) of the Public Health Service Act (42 U.S.C. 300d–41(a)) is amended by striking ''qualified public, nonprofit Indian Health Service, Indian tribal, and urban Indian trauma centers'' and inserting ''qualified public trauma centers, qualified nonprofit trauma centers, and qualified Indian Health Service, Indian tribal, and urban Indian trauma centers''.

(b) TRAUMA CENTER GRANTS QUALIFICATIONS FOR SUBSTANTIAL UNCOMPENSATED CARE COSTS.—Section 1241(b)(3)(B) of the Public Health Service Act (42 U.S.C. 300d–41(b)(3)(B)) is amended—

(1) in clause (i), by striking ''35'' and inserting ''30''; and

(2) in clause (ii), by striking ''50'' and inserting ''40''.

(c) CLARIFICATION RELATING TO TRAUMA CENTER GRANTS.—The heading for part D of title XII of the Public Health Service Act (42 U.S.C. 300d–41 et seq.) is amended to read as follows:

''PART D—TRAUMA CENTERS''.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Texas (Mr. BURGESS) and the gentleman from Texas (Mr. GENE GREEN) each will control 20 minutes.

The Chair recognizes the gentleman from Texas (Mr. BURGESS).

GENERAL LEAVE

Mr. BURGESS. Mr. Speaker, I ask unanimous consent that all Members have 5 legislative days in which to revise and extend their remarks and insert extraneous materials in the RECORD on the bill.

EXHIBIT 18

114TH CONGRESS
1st Session
HOUSE OF REPRESENTATIVES
REPT. 114–41
Part 1

IMPROVING REGULATORY TRANSPARENCY FOR NEW MEDICAL THERAPIES ACT

MARCH 16, 2015.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. UPTON, from the Committee on Energy and Commerce, submitted the following

R E P O R T

[To accompany H.R. 639]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 639) to amend the Controlled Substances Act with respect to drug scheduling recommendations by the Secretary of Health and Human Services, and with respect to registration of manufacturers and distributors seeking to conduct clinical testing, having considered the same, report favorably thereon with amendments and recommend that the bill as amended do pass.

CONTENTS

The amendments are as follows:

Strike all after the enacting clause and insert the following:

49–006

lated to Schedule III, IV, and V drugs that will only be used in clinical trials, H.R. 639 would require the DEA to register the applicant or serve an order to show cause why the applicant shall not be registered within 180 days of the filing of the application. For drugs in Schedule I or II that will only be used in clinical trials, the DEA would be required to issue a notice of application not later than ninety days after an application is accepted for filing. Ninety days after the end of the comment period pursuant to the notice, H.R. 639 would require the DEA to register the applicant or serve an order to show cause on why the registrant should not be registered.

Background and Need for Legislation

During the new drug approval process, FDA examines whether the new drug has abuse potential and, if so, makes a scheduling recommendation through the Assistant Secretary of HHS to the DEA. In formulating its recommendation, the FDA uses an eight part test outlined in section 201(c) of the CSA. Scientific and medical matters related to the scheduling recommendation by the FDA are binding on the DEA. The DEA uses the same eight part test outlined in Section 201(c), but given the binding nature of FDA's findings on scientific and medical matters, the DEA's primary examination rests in three areas: the actual or relative potential for abuse; its history or current patterns of abuse; and the scope, duration, and significance of abuse. Since 1996, the DEA has not made any scheduling decision for a new drug that was contrary to the FDA recommendation.

When a new drug is approved by the FDA, a company can begin marketing the product upon its approval. However, for the subset of drugs that the FDA recommends to the DEA be scheduled, the FDA requires a company attest that they will not market the product until the DEA makes a "final scheduling decision." The attestation is found on HHS Form 356(h). There is no schedule or deadline for the DEA to make a scheduling decision. As such, the FDA can approve a new drug as safe and effective, but patients and physicians must wait to access the newly approved therapy with no expectation of a reasonable timetable in which access will be granted. H.R. 639 would continue to allow DEA to conduct its own analysis, but would remove much of the uncertainty from the process.

The Hatch-Waxman Act of 1984 provided a new drug with five years of data exclusivity after it has been approved as well as eligibility for patent term restoration to compensate for the time taken to receive regulatory approval. The exclusivity starts and the patent term restoration is calculated based on the date of approval for the product. H.R. 639 would clarify that for a new drug that has been recommended to be scheduled by the FDA, the effective date of approval would be the later of the date of FDA approval of the drug product or the date of issuance of an interim final rule by DEA scheduling the new drug. H.R. 639 also would make similar changes to the treatment of animal drugs and biologics. These changes would align the exclusivity and patent term restoration periods with other products that do not need to be scheduled prior to marketing.

Inconsistency and lengthy review times at DEA are not limited to scheduling decisions for new drugs, but also apply to the review

of registration applications submitted by companies in advance of conducting clinical trials. The DEA registration does not distinguish between the manufacturing of a controlled substance for marketing and the manufacturing of a controlled substance for the use in clinical trials. There is no timetable for the DEA to grant approval of registration applications, and there is not a transparent process for the applicant to determine the reasons for a delay in the application. H.R. 639 would bring transparency and predictability to the registration process so companies can properly plan clinical trial schedules for new therapies.

HEARINGS

The Committee on Energy and Commerce held a hearing on January 27, 2015.[1] The Subcommittee received testimony from:

- Mr. Ben D. Chlapek, Deputy Chief, Central Jackson County Fire, Blue Springs, Missouri;
- Mr. John L. Eadie, Director, Prescription Drug Monitoring Program Center of Excellence, Brandeis University;
- Dr. Blaine Enderson, Department of Surgery, University of Tennessee Medical Center;
- Dr. Nathan Fountain, Professor of Neurology, University of Virginia; and,
- Mr. Linden Barber, Partner and Director, DEA Compliance Operations, Quarles & Brady.

COMMITTEE CONSIDERATION

On February 4, 2015, the Subcommittee on Health met in open markup session to consider H.R. 639 and forwarded the bill to the full Committee, as amended, by a voice vote. On February 11 and 12, 2015, the full Committee met in open markup session to consider H.R. 639 and ordered the bill favorably reported to the House, as amended, by a voice vote.

COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list the record votes on the motion to report legislation and amendments thereto. There were no record votes taken in connection with ordering H.R. 639. A motion by Mr. Upton to order H.R. 639 reported to the House, as amended, was agreed to by a voice vote.

COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee held a hearing and made findings that are reflected in this report.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

The objective of this legislation is to facilitate patient access to new therapies in an efficient and transparent manner, while ensuring appropriate controls are in place under the CSA.

[1] H.R. 471 is a reintroduced version of H.R. 4069, the "Ensuring Patient Access and Effective Drug Enforcement of 2013."

EXHIBIT 19

National Security

Justice Department at odds with DEA on marijuana research, MS-13

By Matt Zapotosky and
Devlin Barrett
August 15, 2017

The Justice Department under Attorney General Jeff Sessions has effectively blocked the Drug Enforcement Administration from taking action on more than two dozen requests to grow marijuana to use in research, one of a number of areas in which the anti-drug agency is at odds with the Trump administration, U.S. officials familiar with the matter said.

A year ago, the DEA began accepting applications to grow more marijuana for research, and as of this month it had 25 proposals to consider. But DEA officials said they need the Justice Department's approval to move forward. So far, the department has not been willing to provide it.

"They're sitting on it," said one law enforcement official familiar with the matter. "They just will not act on these things."

As a result, said one senior DEA official, "the Justice Department has effectively shut down this program to increase research registrations."

DEA spokesman Rusty Payne said the agency "has always been in favor of enhanced research for controlled substances such as marijuana."

Lauren Ehrsam, a Justice Department spokeswoman, declined to comment.

The standoff is the latest example of the nation's premier narcotics enforcement agency finding itself in disagreement with the new administration. While President Trump and Sessions have vowed a crackdown on drugs and violent crime, DEA officials have publicly and privately questioned some of the administration's statements and goals.

Late last month, acting DEA administrator Chuck Rosenberg wrote in an email to staff members that Trump had "condoned police misconduct" in remarking to officers on Long Island that they need not protect suspects' heads when putting them into police vehicles. The acting administrator said he was writing his employees "because we have an obligation to speak out when something is wrong." After public criticism, White House officials said the president was joking.

DEA officials say Sessions and his Justice Department have pressed the agency for action specifically on MS-13 despite warnings from Rosenberg and others at the DEA that the gang, which draws Central American

teenagers for most of its recruits, is not one of the biggest players when it comes to distributing and selling narcotics.

Mexican cartels, DEA officials have warned, will use any gang to sell their drugs, and DEA leaders have directed those in their field offices to focus on the biggest threat in their particular geographic area. In many parts of the country, MS-13 simply does not pose a major criminal or drug-dealing threat compared with other groups, these officials said.

The officials spoke on the condition of anonymity because they could face professional consequences for candidly describing the internal disputes.

“Mexican cartels, Mexican transnational organizations are the greatest criminal threat to the United States,” Payne, the DEA spokesman, said. “There’s no other group currently positioned to challenge them. Whenever drug investigations that we do involve MS-13, we respond, but right now the No. 1 drug threat in the U.S. is the Mexican cartels.”

Sessions frequently speaks harshly about marijuana use, and Justice Department officials have been reviewing the policy of his predecessor when it comes to enforcing federal laws on marijuana in states where the drug is legal. Sessions, too, has called medical marijuana “hyped, maybe too much,” and signaled that he is skeptical about the benefits of smoking it.

“Dosages can be constructed in a way that might be beneficial, I acknowledge that, but if you smoke marijuana, for example, where you have no idea how much THC you’re getting, it’s probably not a good way to administer a medicinal amount. So forgive me if I’m a bit dubious about that,” Sessions said earlier this year.

The DEA is no shrinking violet when it comes to marijuana enforcement. Last year, Rosenberg declined to lessen restrictions on its use, maintaining its classification as a Schedule 1 controlled substance — which means it has no accepted medical use and a high potential for abuse.

But Rosenberg wrote at the time that the DEA would “support and promote legitimate research regarding marijuana and its constituent parts.” The DEA, he wrote, already had approved such research, registering 354 people and institutions to study marijuana and related components, including the effects of smoked marijuana on humans.

The DEA indicated at the time it was willing to see those studies expand, asking for applications from people who wanted to grow marijuana to be used for research. The only source of marijuana for researchers then was — and is — the University of Mississippi, which has permission to grow and distribute the drug for research.

One still-waiting applicant is Lyle Craker, a professor at the University of Massachusetts at Amherst. Craker has spent years seeking approval to do research into whether other parts of marijuana plants have medicinal value.

"I've filled out the forms, but I haven't heard back from them. I assume they don't want to answer," Craker said. "They need to think about why they are holding this up when there are products that could be used to improve people's health. I think marijuana has some bad effects, but there can be some good, and without investigation we really don't know."

Craker submitted his latest application Feb. 14; after getting additional questions from the DEA in March, he supplied additional information in April.

Brad Burge, spokesman for the Multidisciplinary Association for Psychedelic Studies, said that the federal government for years has prevented important research into marijuana.

"That's a sad state of affairs," he said. "If the DEA is now asking for permission to say yes, then the resistance is now further up the chain of command."

Rosenberg indicated in a call with The Washington Post that he still would support more marijuana research.

"I stand by what I wrote," he said.

Tension between Rosenberg and Trump is perhaps unsurprising. Rosenberg was appointed during the Obama administration, and he had served as chief of staff and senior counselor to James B. Comey, who was the FBI director until Trump fired him earlier this year.

The Justice Department has not rejected any of the 25 people whose applications to grow marijuana the DEA is considering. Rather, the department is not taking any action at all, officials said. Before approving such applications, DEA officials have to assess each applicant and determine whether their facility is secure and whether they had previously been complying with federal law.

Matt Zapotosky
Matt Zapotosky covers the Justice Department for The Washington Post's national security team. He has previously worked covering the federal courthouse in Alexandria and local law enforcement in Prince George's County and Southern Maryland. Follow

Devlin Barrett
Devlin Barrett writes about national security and law enforcement for The Washington Post. He has previously worked at the Wall Street Journal, the Associated Press and the New York Post, where he started as a copy boy. Follow

EXHIBIT 20

https://www.wsj.com/articles/marijuana-research-applications-go-nowhere-at-justice-department-1536404401

U.S.

Marijuana-Research Applications Go Nowhere at Justice Department

Sessions is longtime critic of pot use, though he has voiced support for research on drug

Attorney General Jeff Sessions has long been opposed to marijuana use, but he has signalled openness to research on the drug.
PHOTO: JIM LO SCALZO/EPA-EFE/REX/SHUTTE/EPA/SHUTTERSTOCK

By Sadie Gurman

Sept. 8, 2018 7:00 a.m. ET

Two years after the Drug Enforcement Administration began accepting requests to grow marijuana for federally approved research, none have been answered, leaving more than two dozen applicants in limbo, people familiar with the process said.

The future of the initiative ultimately rests with the DEA's parent agency, the Justice Department, and officials under Attorney General Jeff Sessions, a longtime critic of marijuana use, aren't eager to advance the applications, these people said. Mr. Sessions has stated publicly he is open to research on the drug but has offered no timeline for processing the applications.

An employee stocked cannabis at a San Francisco store earlier this year. **PHOTO:** NOAH BERGER/ASSOCIATED PRESS

The applicants include a variety of entrepreneurs, as well as a university professor and a former Navy SEAL who wants to study how marijuana might help veterans suffering from chronic pain and post-traumatic stress.

Republican and Democratic lawmakers have voiced frustration at the delays, saying Mr. Sessions has repeatedly avoided questions about the status of the applications. The inaction, they say, is stalling much-needed research into the potential health benefits of marijuana as society takes a more tolerant view of its use.

A DEA spokeswoman referred questions to the Justice Department, which declined to comment.

A growing number of states have legalized marijuana in recent years for medical or recreational purposes, generating support for the issue from both parties. But pot remains prohibited under federal law, creating a legal gray area that has made it hard to pursue federally approved research.

The evolving political landscape has turned some law-and-order Republicans into advocates for their states' rights to develop a marijuana industry. It has made unlikely allies of lawmakers such as Sens. Kamala Harris (D., Calif.), and Orrin Hatch (R., Utah), who last week wrote Mr. Sessions for at least the third time urging him to take action on the applications. A bipartisan group of House lawmakers also queried Mr. Sessions last week but received no response.

"It is imperative that our nation's brightest scientists have access to diverse types of federally-approved, research-grade marijuana to research both its adverse and therapeutic effects," Sens. Harris and Hatch wrote.

California this year started what could become the world's largest legal recreational marijuana market. Utah still forbids the drug, but a ballot measure would legalize it for medical purposes, and Mr. Hatch has been a vocal supporter of research.

The DEA under President Obama began seeking applications for new marijuana researchers in August 2016, saying it "fully supports expanding research into the potential medical utility of marijuana and its chemical constituents."

At least 26 applications have been submitted since then. None have been approved or rejected, and applicants say they have seen little sign of any movement.

DEA officials believed their push to expand research complied with federal law. But the Trump administration threw the effort into doubt by asking the Justice Department's Office of Legal Counsel to review the policy's legality, the people familiar with the matter said. Officials concluded it violated a 1961 United Nations treaty that aims to curb drug trafficking.

Last spring, Justice Department lawyers privately floated a new policy to expand research that included significant additional restrictions. But DEA officials found it convoluted, saying it would strain the agency's resources and be almost impossible to implement, one person familiar with the discussion said. The effort has since been on hold.

It isn't the first time Mr. Sessions has parted ways with members of his own party when it comes to marijuana. GOP Colorado Sen. Cory Gardner earlier this year said he would block Justice Department nominees from moving through the Senate after Mr. Sessions changed DOJ policy to give federal prosecutors more room to pursue marijuana-related cases. He later lifted his blockade.

Individual applications are weighed by the head of the DEA, acting administrator Uttam Dhillon, but lawmakers say it is Mr. Sessions's view that matters. It is unclear where Mr. Dhillon, a former federal prosecutor who previously led antidrug efforts at the Homeland Security department, stands on marijuana research.

Adding to their concerns, some research applicants worry that if Mr. Sessions were to leave office—he is regularly criticized by President Trump—the research process would be further slowed.

The U.S. government for decades has considered a farm at the University of Mississippi, which grows pot under a contract with the National Institute on Drug Abuse, the only legal source of marijuana for federal research. Researchers say they need to study a wider variety of the drug to know if it can be effective in alleviating pain, fighting seizures, combating depression and relieving post-traumatic stress.

"The federal government allows for multiple entities to produce controlled substances for scientific research all the time. Why should marijuana be any different?" said George Hodgin, a former Navy SEAL who started his own business, Biopharmaceutical Research Company, to conduct such research.

Mr. Hodgin became interested in medical marijuana after a fellow veteran considered using it as part of his rehabilitation and learned research was scarce. He applied to the DEA in early 2017.

In October, Mr. Sessions told a congressional committee it would be "healthy" to have more competition, though he doubted the need to approve all 26 applications. In April, he told lawmakers the Justice Department was moving ahead with the effort to expand research and would soon add additional suppliers.

"There may well be some benefits to medical marijuana, and it's perfectly appropriate to study it," Mr. Sessions said.

But for now, the delay leaves entrepreneurs like Mr. Hodgin unable to proceed. "America should be first in the world in researching novel treatments, in a compliant fashion, for our veterans and suffering patients," he said.

Write to Sadie Gurman at sadie.gurman@wsj.com

EXHIBIT 21

FEBRUARY 8, 2018 9:22PM ET

Why Is it So Hard to Study Pot?

The DEA announced they would "streamline" applications for scientific studies of cannabis – but experts say that won't change anything

By **ERIC KILLELEA**

Earlier this year, the Drug Enforcement Administration **announced** it is "streamlining" a research application process for studying Schedule I drugs, including ecstasy and LSD. The news release failed to mention cannabis, which has also been lumped into the classification the federal agency created for substances having "no accepted medical use and a high potential for abuse."

So what does this mean? In an email, DEA spokesperson Katherine Pfaff tells *Rolling Stone* that the federal agency "moved their application process to a completely electronic process, eliminating the need to mail in all initial or renewal applications." In effect, the update means to "help all researchers by improving and expediting the process." While acting DEA Administrator Robert W. Patterson said in the press release that "research is the bedrock of science," non-profit organizations and scientists specifically researching cannabis believe the transition from postal mail to email won't change much for those jumping through statutory and regulatory hoops to study a drug already deemed beneficial for medical purposes by the **National Academy of Sciences** and in peer-reviewed **studies**.

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During a recent interview, John Hudak, a senior fellow of governance at **Brookings Institution**, explained to *Rolling Stone* that, in order for anyone to conduct research on Schedule I drugs, they must acquire a license from the DEA that shows they're certified to work with such substances. (Over 590 researchers registered with the DEA to study Schedule I substances.) "Bringing this process online is, of course, a positive step, but it's a very small drop in the bucket and there are so many significant barriers for researchers still," Hudak says. "It's equivalent of shortening the Daytona 500 by 10 inches."

Many non-profit organizations see the DEA's efforts as falling short of fixing actual problems with cannabis research. **National Organization for the Reform of Marijuana Laws** (NORML) deputy director Paul Armentano tells *Rolling Stone* that he "doesn't foresee the directive from the DEA having any significant impact with regard to the facilitation of clinical trials involving cannabis."

expert.

Today, studies require approval from three federal agencies before moving forward on a clinical trial: the DEA, the Food and Drug Administration, and the National Institute on Drug Abuse, Armentano says. (The overwhelming majority of studies include observational trials – i.e., using subjects who procure their own marijuana – which don't need federal approval since no administration of cannabis takes place.) And in order for a drug to go to market, there **must be at least one** randomized, double-blind, placebo-controlled clinical trials – which is not an easy process.

For one, marijuana is subject to its own regulations separate from those governing other Schedule I drugs. While LSD researchers can acquire products from private manufacturers licensed to produce and dispense controlled substances, those studying cannabis can only acquire their products from NIDA and the **University of Mississippi**, the lone legal marijuana grower and distributor in the U.S. since 1968.

Morgan Fox, communications manager for the **Marijuana Policy Project**, tells *Rolling Stone* that researchers have "long been going through the gauntlet" for federal approval. "And those approved to get research products from the fed farm in Mississippi get the lowest quality of marijuana ever seen, and it's often not usable for research purposes," Fox says.

What's wrong with the Ole Miss marijuana? As Armentano sees it, NIDA-sourced cannabis is "often not reflective of cannabis consumed by the general population." One issue is that the federal

An irony here is that a California-based researcher who wants to study the impacts of cannabis on, say, concentration and cognition, can't use the medical or recreational marijuana legalized in-state if they want to perform a clinical trial. "If you're in a state where marijuana is legal and commercially grown under a state license and tested at a state lab, researchers still have to use marijuana from NIDA," Armentano says. "That is the legal hurdle that exists for cannabis that doesn't exist for other in substances."

"Science shouldn't be shackled by politics," says Dr. Sue Sisley, a researcher at the California-based Multidisciplinary Association for Psychedelic Studies. It took seven years before the federal government approved Sisley to start the **first ever trial** of medical marijuana for post-traumatic stress disorder in military veterans. Then last year, after waiting another 20 months to get NIDA-sourced cannabis, she discovered that some samples were contaminated with **mold** and others didn't match the potency levels she requested. The **study** eventually moved forward, but only after the researchers conducted their own testing of the products. "We were the first research team to do secondary testing on the NIDA cannabis because we wanted to ensure it was safe to administer to study subjects," says Sisley, adding that she's a lifelong Republican who has been approaching members of Congress about the need for more research options. "It should be politically safe to discuss, but it's often not."

For Hudak, he believes regulations covering science need to catch up to domestic markets. "It's critically important to study marijuana because over 200 million Americans live in states with full-fledge medical marijuana programs," he says. "The University of Mississippi is trying to keep up, but the private market will always be a step ahead of the government and the lag in the catchup is profound."

There's much blame to go around regarding research roadblocks. A change in DEA rules two years ago sought to allow alternative producers and received at least 25 applications to grow marijuana for research. The DEA needed approval from the Justice Department to get things rolling. But last year, Attorney General Jeff Sessions, a longtime vocal opponent of marijuana, **shut down any movement**.

"The legal hurdle that exists for cannabis that doesn't exist for other in substances," says NORML's Armentano.

While some research advocates continue to point fingers at Sessions, others don't buy the notion of a **DEA v. DOJ standoff**. "The DEA has tried to shift the blame to Sessions, but the DEA is the agency that sets the quota for how much marijuana is grown in this country and signs off on licensing for researchers," Armentano says. "Now the DEA wants to say they're open to research? That sounds disingenuous as hell to me."

At the end of the day, most know that "Sessions does not like marijuana and doesn't want to do anything to forward progress," Fox says. But many have lost faith in the DEA's efforts to ease cannabis research even though "there's "a lot of people in government agencies that see the ridiculousness of restricting research options and see a need for small scale changes that could have large scale impacts," Hudak says.

Is there any room for optimism? "I have heard lip service from every agency and every politician you can imagine and there's no political interest to change," Armentano says. "Yes, there's perfunctory Congressional bills, but the bills are so convoluted." One way of getting around the NIDA-sourced cannabis is importing legal, standardized cannabis from Canada, which permits legal exports to countries such as Australia, Germany and New Zealand – but that's not likely. "Consider importing from Canada," says Armentano. "It's legal and allows exportation of cannabis. The DEA can sign off on an import license. But the ultimate problem is science and research don't drive the narrative in the U.S. and it's so far out of the government's comfort zone" that it probably would never happen.

Still, researchers continue to fight inside the box of federal restrictions. "It's important to remember that researchers across the country here are still willing to go through the hoops and use NIDA marijuana for clinical trials," Armentano says.

In This Article: War on Drugs

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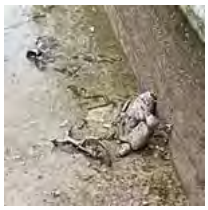

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EXHIBIT 22

U.S. Department of Justice
Drug Enforcement Administration

Office of the Administrator *Springfield, VA 22152*

August 11, 2016

The Honorable Gina M. Raimondo
Governor of Rhode Island
82 Smith Street
Providence, Rhode Island 02903

The Honorable Jay R. Inslee
Governor of Washington
P.O. Box 40002
Olympia, Washington 98504-0002

Mr. Bryan A. Krumm
[redacted]

Dear Governor Raimondo, Governor Inslee, and Mr. Krumm:

The enclosed materials provide the legal and factual bases for our decision, in response to your petitions, regarding the rescheduling of marijuana.[1] I will get to that decision, but I will first highlight broader considerations with respect to (1) the law regarding drug scheduling and (2) the current state of marijuana research.

The Law Regarding Drug Scheduling:

The Controlled Substances Act (CSA) mandates that scheduling decisions be based on medical and scientific data and other data bearing on the relative abuse potential of the drug. Under the CSA, the Food and Drug Administration (FDA), in consultation with the National Institute on Drug Abuse (NIDA), reviews, analyzes, and assesses that data and its medical and scientific conclusions legally bind the Drug Enforcement Administration (DEA).

The FDA and the DEA make a determination based on a full review of the relevant scientific and medical literature regarding marijuana. That process, too, is outlined in the enclosed materials.

A substance is placed in Schedule I if it has no currently accepted medical use in treatment in the United States, a lack of accepted safety for use under medical supervision, and a high potential for abuse. These criteria are set by statute.

[1] Governors Raimondo and Inslee succeeded petitioner Governors Chafee and Gregoire, respectively.

Schedule I includes some substances that are exceptionally dangerous and some that are less dangerous (including marijuana, which is less dangerous than some substances in other schedules). That strikes some people as odd, but the criteria for inclusion in Schedule I is not relative danger.

In that sense, drug scheduling is unlike the Saffir-Simpson scale or the Richter scale. Movement up those two scales indicates increasing severity and damage (for hurricanes and earthquakes, respectively); not so with drug scheduling. It is best not to think of drug scheduling as an escalating "danger" scale – rather, specific statutory criteria (based on medical and scientific evidence) determine into which schedule a substance is placed.

Marijuana Research:

Research is the bedrock of science, and we will – as we have for many years – support and promote legitimate research regarding marijuana and its constituent parts. For instance, DEA has never denied an application from a researcher to use lawfully produced marijuana in a study determined by the Department of Health and Human Services (HHS) to be scientifically meritorious.

In fact, during the last two plus years, the total number of individuals and institutions registered with DEA to research marijuana, marijuana extracts, derivatives, and tetrahydrocannabinols (THC) has more than doubled, from 161 in April 2014 to 354 at present. Some of the ongoing research includes studies of the effects of smoked marijuana on human subjects. Folks might be surprised to learn that we support this type of research. But, we do.

DEA and NIDA have also increased the amount of marijuana available for research. Indeed, we consistently meet legitimate demand by researchers for marijuana. Currently, NIDA is filling requests for research marijuana in an average of 25 days.

We will continue to work with NIDA to ensure that there is a sufficient supply of marijuana and its derivatives (in terms of quantity and the variety of chemical constituents) to support legitimate research needs. This includes approving additional growers of marijuana to supply researchers. Details of this proposal to support legitimate research will be published in the Federal Register.

Further, in December 2015, we waived certain regulatory requirements for researchers conducting FDA-authorized clinical trials on cannabidiol (CBD), a constituent part of marijuana. These waivers, when granted, enable researchers to modify or expand the scope of their studies more easily. Currently, there are 90 researchers registered with the DEA to conduct CBD research on human subjects. We have approved every waiver application that has been submitted by these researchers – to date, a total of 47.

If, for instance, CBD proves to be safe and effective for the treatment of a specific medical condition, such as childhood epilepsy (some trials have shown promise), that would be a wonderful and welcome development. But we insist that CBD research – or any research – be sound, scientific, and rigorous before a product can be authorized for medical use. That is specifically – and properly – the province of the FDA.

DEA continues to work on other measures to support marijuana research. For instance, DEA is building an online application system for researchers to apply for Schedule I research registrations, including for marijuana. DEA also is drafting clear guidance to assist Schedule I researchers in that application process.

The Decision:

The FDA drug approval process for evaluating potential medicines has worked effectively in this country for more than 50 years. It is a thorough, deliberate, and exacting process grounded in science, and properly so, because the safety of our citizens relies on it.[2]

Using established scientific standards that are consistent with that same FDA drug approval process and based on the FDA's scientific and medical evaluation, as well as the legal standards in the CSA, marijuana will remain a schedule I controlled substance. It does not have a currently accepted medical use in treatment in the United States, there is a lack of accepted safety for its use under medical supervision, and it has a high potential for abuse.

If the scientific understanding about marijuana changes – and it could change – then the decision could change. But we will remain tethered to science, as we must, and as the statute demands. It certainly would be odd to rely on science when it suits us and ignore it otherwise.

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[2] The FDA's scientific assessment determines the safety and efficacy of drugs intended for human consumption. The FDA's team, charged with conducting that assessment, consists of clinical pharmacologists, epidemiologists, toxicologists, physicians, chemists, statisticians and other scientists, working together to ensure approved drugs are safe and effective. As our partners at HHS note, "[An] expert [in this discipline] is an individual qualified by scientific training and experience to evaluate the safety and effectiveness of a drug." Although medical doctors are highly trained and qualified to treat patients with FDA-approved drugs, as HHS notes, "[m]edical practitioners who are not experts in evaluating drugs are not qualified to determine whether a drug is generally recognized as safe or effective or meets NDA (New Drug Application) requirements." 57 FR 10499. Simply put, evaluating the safety and effectiveness of drugs for their intended use is a highly specialized endeavor undertaken by the FDA's Center for Drug Evaluation and Research.

The DEA and FDA continue to believe that scientifically valid and well-controlled clinical trials conducted under investigational new drug applications are the proper way to research all potential new medicines, including marijuana. Furthermore, we believe that the drug approval process is the proper way to assess whether a product derived from marijuana or its constituent parts is safe and effective for medical use.

We fully support legitimate medical and scientific research on marijuana and its constituent parts and we will continue to seek ways to make the process for those researchers more efficient and effective.

Sincerely,

Chuck Rosenberg
Acting Administrator

Enclosures

EXHIBIT 23

IMPROVING PREDICTABILITY AND TRANSPARENCY IN DEA AND FDA REGULATION

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

ONE HUNDRED THIRTEENTH CONGRESS

SECOND SESSION

APRIL 7, 2014

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Mr. PITTS. This committee has taken steps to provide more transparency and consistency in the drug approval process through the Prescription Drug User Fee Program and a commitment to review goals imbedded in the PDUFA agreements. However, drugs that contain substances that have not been previously marketed in the United States and that have abuse potential must also be scheduled under the CSA by the DEA before they can begin marketing their product. But under the CSA, there is no deadline for the DEA to make a scheduling decision, and the delays in DEA decisions have increased nearly fivefold since the year 2000. This lack of predictability in the timing of DEA's scheduling decisions leads to unnecessary uncertainty in the drug development process and needless delays in patients' access to new therapies.

H.R. 4299 simply requires the DEA to issue an interim final rule 45 days after it receives FDA's scheduling recommendation for a new drug, allowing patients access to new therapies 45 days after FDA approval. DEA would retain its authority to subsequently transfer the drug between schedules under the Section 201 of the CSA.

This bill also establishes a timeline for DEA to grant approval of manufacturers' applications to register controlled substances not yet approved by FDA to be used in clinical trials, allowing companies to properly plan clinical trial schedules for prospective new therapies. This provision will get products to the market faster because innovators will be able to get clinical trials under way in a timely and predictable way, which is critical to drug developers and patients alike.

H.R. 4299 requires that if the DEA has not made a final decision on whether to approve a registration application for products in the investigational new drug, IND, phase within 180 days of submission of the application, then the DEA shall provide notice to the applicant on the outstanding issues that must be resolved in order to reach a final decision and an estimated date on which a final decision on the registration application will be made.

Such a solution does not force the DEA to make a particular decision but will provide transparency to the process so companies can better plan when regulatory decisions will be made.

I would like to thank all of our witnesses for being here today. I look forward to having a constructive discussion on these legislative proposals. These bills touch on very important issues for this committee, and they offer and excellent starting point for finding solutions.

[The prepared statement of Mr. Pitts follows:]

PREPARED STATEMENT OF HON. JOSEPH R. PITTS

Today's legislative hearing focuses on three bills designed to improve the predictability and transparency in Drug Enforcement Administration (DEA) and Food and Drug Administration (FDA) regulation:

- H.R. 4069, the Ensuring Patient Access and Effective Drug Enforcement Act, introduced by Reps. Marino and Blackburn, will facilitate greater collaboration between industry stakeholders and regulators in an effort to combat our Nation's prescription drug abuse epidemic;
- H.R. 4250, the Sunscreen Innovation Act, introduced by Reps. Whitfield and Dingell, seeks to expedite the FDA's approval process for active ingredients in sunscreens that have long been approved for use in places like Europe, Canada, and